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The President

Revised List of Quarantinable Communicable Diseases

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 264(b) of title 42, United States Code, it is hereby ordered as follows:

Section 1. *Amendment to Executive Order 13295.* Based upon the recommendation of the Secretary of Health and Human Services, in consultation with the Acting Surgeon General, and for the purposes set forth in section 1 of Executive Order 13295 of April 4, 2003, as amended by Executive Order 13375 of April 1, 2005, section 1 of Executive Order 13295 shall be further amended by replacing subsection (b) with the following:

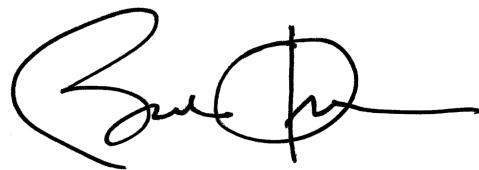
“(b) Severe acute respiratory syndromes, which are diseases that are associated with fever and signs and symptoms of pneumonia or other respiratory illness, are capable of being transmitted from person to person, and that either are causing, or have the potential to cause, a pandemic, or, upon infection, are highly likely to cause mortality or serious morbidity if not properly controlled. This subsection does not apply to influenza.”

Sec. 2. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

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

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

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



THE WHITE HOUSE,
July 31, 2014.

Rules and Regulations

Federal Register

Vol. 79, No. 151

Wednesday, August 6, 2014

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 945

[Doc. No. AMS-FV-14-0046; FV14-945-2 IR]

Irish Potatoes Grown in Certain Designated Counties in Idaho, and Malheur County, Oregon; Modification of Container Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim rule with request for comments.

SUMMARY: This rule modifies the container requirements currently prescribed under the Idaho-Eastern Oregon potato marketing order (order). The order regulates the handling of potatoes grown in certain designated counties in Idaho, and Malheur County, Oregon and is administered locally by the Idaho-Eastern Oregon Potato Committee (Committee). This rule removes the requirement that fiberboard cartons used to pack 50-pound quantities of U.S. No. 2 grade potatoes be of one-piece construction. This change is needed to respond to market demands and to provide handlers flexibility in shipping U.S. No. 2 grade potatoes. In addition, this rule makes a change to the order's handling regulations to correct a citation reference.

DATES: August 7, 2014; comments received by October 6, 2014 will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA, 1400 Independence Avenue SW., STOP

0237, Washington, DC 20250-0237; Fax: (202) 720-8938; or Internet: <http://www.regulations.gov>. All comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: <http://www.regulations.gov>. All comments submitted in response to this rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Sue Coleman, Marketing Specialist, or Gary D. Olson, Regional Director, Northwest Marketing Field Office, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA; Telephone: (503) 326-2724, Fax: (503) 326-7440, or Email: Sue.Coleman@ams.usda.gov or GaryD.Olson@ams.usda.gov.

Small businesses may request information on complying with this regulation by contacting Jeffrey Smutny, Marketing Order and Agreement Division, Fruit and Vegetable Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250-0237; Telephone: (202) 720-2491, Fax: (202) 720-8938, or Email: Jeffrey.Smutny@ams.usda.gov.

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement No. 98 and Order No. 945, both as amended (7 CFR part 945), regulating the handling of Irish potatoes grown in certain designated counties in Idaho, and Malheur County, Oregon, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the "Act."

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 12866, 13563, and 13175.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file

with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This rule modifies language in the order's administrative rules and regulations to remove the requirement that fiberboard cartons used to pack 50-pound quantities of U.S. No. 2 grade potatoes must be of one-piece construction. This change will allow handlers to ship U.S. No. 2 grade potatoes in 50-pound fiberboard cartons without regard to the construction of the carton. The requirement that cartons be of natural kraft color and be permanently and conspicuously marked as to grade will not change as a result of this rule. This rule will enable handlers to respond to market demands and provide greater flexibility in shipping U.S. No. 2 grade potatoes. This rule was unanimously recommended at a Committee meeting on April 22, 2014. In addition, this rule makes a change to the order's handling regulations to correct references in § 945.341(b)(3)(i) and (ii), which currently refers to a paragraph that does not exist: (b)(4)(iii). The correct reference should be (b)(3)(iii).

Sections 945.51 and 945.52 of the order provide authority for the establishment and modification of regulations applicable to the handling of potatoes. Section 945.52(a)(3) specifically authorizes the regulation of size, capacity, weight, dimensions, pack, labeling or marking of the container, or containers, which may be used in the packaging or handling of potatoes, or both.

Section 945.341 of the order's administrative rules prescribes the minimum quality, minimum maturity, pack and marking, and inspection requirements for handling fresh market Idaho-Eastern Oregon potatoes. Section 945.341(c) prescribes the pack and

marking requirements for domestic and export shipments of potatoes. Under those requirements, cartons of U.S. No. 2 grade potatoes must be packed in one-piece 50-pound fiberboard cartons of natural kraft color provided the cartons are permanently and conspicuously marked as to grade. Grade requirements are based on the U.S. Standards for Grades of Potatoes (7 CFR 51.1540–51.1566).

At its telephone meeting on April 22, 2014, the Committee unanimously recommended the relaxation of the order's container requirements to remove the one-piece construction prerequisite for 50-pound fiberboard cartons. The change was recommended to allow handlers to ship U.S. No. 2 grade potatoes in any type of 50-pound fiberboard cartons of natural kraft color, provided the cartons are permanently and conspicuously marked as to grade.

Handlers reported that food service customers are very concerned about the one-piece 50-pound cartons because they are often damaged in transit. The one-piece 50-pound carton has a structure that is weaker than that of a two-piece 50-pound carton with a bottom and a lid. Despite the structure, the two-piece 50-pound carton is less costly than the one-piece construction and could save handlers between \$400 and \$1,600 per load, depending on the transportation method utilized.

Additionally, handlers expressed the need for the mandatory grade markings to only be required on the top portion of a multi-piece 50-pound carton. This would enable handlers to save money by allowing them to use a uniform, unmarked bottom piece for different grades of potatoes. The lid of the multi-piece 50-pound carton would continue to be required to have the grade permanently and conspicuously marked.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 450 producers of potatoes in the production area and approximately 32 handlers subject to regulation under the marketing order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts of less than \$750,000, and small agricultural service firms are defined as those whose annual receipts are less than \$7,000,000 (13 CFR 121.201).

During the 2012–2013 fiscal period, the most recent for which statistics are available, 35,148,900 hundredweight of Idaho-Eastern Oregon potatoes were inspected under the order and sold into the fresh market. Based on information provided by the National Agricultural Statistics Service, the average producer price for the 2012 Idaho potato crop was \$5.30 per hundredweight. Multiplying \$5.30 by the shipment quantity of 35,148,900 hundredweight yields an annual crop revenue estimate of \$186,289,170. The average annual fresh potato revenue for each of the 450 producers is therefore calculated to be \$413,396 (\$186,289,170 divided by 450), which is less than the SBA threshold of \$750,000. Consequently, on average almost all of the Idaho-Eastern Oregon potato producers may be classified as small entities.

In addition, based on information reported by USDA's Market News Service, the average f.o.b. shipping point price for the 2012 Idaho potato crop was \$5.87 per hundredweight. Multiplying \$5.87 by the shipment quantity of 35,148,900 hundredweight yields an annual crop revenue estimate of \$206,324,043. The average annual fresh potato revenue for each of the 32 handlers is therefore calculated to be \$6,447,626 (\$206,324,043 divided by 32), which is less than the SBA threshold of \$7,000,000. Consequently, on average most all of the Idaho-Eastern Oregon potato handlers may be classified as small entities.

This rule relaxes the container requirements to allow handlers to ship U.S. No. 2 grade potatoes in any type of 50-pound fiberboard cartons of natural kraft color, provided the cartons are permanently and conspicuously marked as to grade. This will enable handlers to respond to market demands and to provide greater flexibility in shipping U.S. No. 2 grade potatoes. In addition, this rule makes changes to the order's handling regulations to correct a citation reference.

The authority for the establishment of pack and marking requirements is provided in § 945.52 of the order. Section 945.341(c) of the order's administrative rules prescribes the pack

and marking requirements for domestic and export shipments of potatoes.

The Committee believes that the recommendation should increase the sale of U.S. No. 2 grade potatoes. This action is expected to further increase the shipments of U.S. No. 2 potatoes to the food service industry and help the Idaho-Eastern Oregon potato industry benefit from the recent increased growth in demand from the food service industry sector. The benefits of this rule are not expected to be disproportionately greater or lesser for small entities than large entities.

Prior to arriving at this container recommendation, the Committee considered information from the Idaho Potato Commission and the Idaho Grower Shippers Association. The Committee also discussed several alternatives to this recommendation including leaving the current requirement in place. However, the Committee believed that it was important to be able to respond to changing market conditions and meet customer needs. The Committee will monitor the quantity of U.S. No. 2 grade potatoes shipped in multi-piece 50-pound fiberboard cartons of natural kraft color and evaluate if any further modification to the order's container requirements is necessary.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0178 (Generic Vegetable and Specialty Crops). No changes in those requirements as a result of this action are necessary. Should any changes become necessary, they would be submitted to OMB for approval.

This rule will not impose any additional reporting or recordkeeping requirements on either small or large Idaho-Eastern Oregon potato handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

In addition, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this rule.

Further, the Committee meeting was widely publicized throughout the Idaho-Eastern Oregon potato industry and all interested persons were invited to attend the meeting and participate in Committee deliberations. Like all Committee meetings, the April 22, 2014, meeting was a public meeting and all entities, both large and small, were able to express their views on this issue. Finally, interested persons are invited to submit comments on this interim rule, including the regulatory and informational impacts of this action on small businesses.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <http://www.ams.usda.gov/MarketingOrdersSmallBusinessGuide>. Any questions about the compliance guide should be sent to Jeffrey Smutny at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

This rule invites comments on a change to the container requirements currently prescribed under the Idaho-Eastern Oregon potato marketing order. Any comments received will be considered prior to finalization of this rule.

After consideration of all relevant material presented, including the Committee's recommendation, and other information, it is found that this interim rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) Handlers are currently shipping Idaho-Eastern Oregon potatoes; (2) this action relaxes current container requirements; (3) the Committee unanimously recommended this change at a public meeting and interested parties had an opportunity to provide input; and (4) this rule provides a 60-day comment period and any comments received will be considered prior to finalization of this rule.

List of Subjects in 7 CFR Part 945

Marketing agreements, Potatoes, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 945 is amended as follows:

PART 945—IRISH POTATOES GROWN IN CERTAIN DESIGNATED COUNTIES IN IDAHO, AND MALHEUR COUNTY, OREGON

■ 1. The authority citation for 7 CFR part 945 continues to read as follows:

Authority: 7 U.S.C. 601–674.

§ 945.341 [Amended]

■ 2. In § 945.341(b)(3)(i) and (ii), remove the reference “(b)(4)(iii)” and add in its place the reference “(b)(3)(iii)”.

■ 3. In § 945.341(c)(2)(ii), remove the word “one-piece”.

Dated: July 31, 2014.

Rex A. Barnes,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2014–18606 Filed 8–5–14; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 732, 738, 740, 742, 744, 746 and 774

[Docket No. 140729634–4638–01]

RIN 0694–AG25

Russian Oil Industry Sanctions and Addition of Person to the Entity List

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) by adding one person to the Entity List. The person who is added to the Entity List is located in Russia and has been determined by the U.S. Government to be acting contrary to the national security or foreign policy interests of the United States. This person will be listed on the Entity List under the destination of Russia.

This rule also imposes controls on certain items for use in Russia's energy sector intended for energy exploration or production from deepwater (greater than 500 feet), Arctic offshore, or shale projects.

DATES: *Effective date:* This rule is effective August 6, 2014.

FOR FURTHER INFORMATION CONTACT: For the change to Russia licensing policy contact Eileen Albanese, Director, Office of National Security and Technology Transfer Controls, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482–0092, Fax: (202) 482–

3355, Email: rp22@bis.doc.gov. For emails, include “Russia” in the subject line.

For the Entity List-related changes contact the Chair, End-User Review Committee, Office of the Assistant Secretary, Export Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482–5991, Fax: (202) 482–3911, Email: ERC@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Background

In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) to impose additional sanctions implementing U.S. policy toward Russia to address that country's continuing policy of destabilization in Ukraine and continuing occupation of Crimea and Sevastopol. Specifically, in this rule BIS adds one person to the Entity List. In addition, this rule imposes controls on certain items for use in Russia's energy sector intended for exploration or production from deepwater (greater than 500 feet), Arctic offshore, or shale projects that have the potential to produce oil or gas in Russia.

A. The Entity List

The Entity List (Supplement No. 4 to Part 744) notifies the public about entities that have engaged in activities that could result in an increased risk of the diversion of exported, reexported or transferred (in-country) items to weapons of mass destruction (WMD) programs, activities sanctioned by the State Department and activities contrary to U.S. national security or foreign policy interests, including terrorism and export control violations involving abuse of human rights. Certain exports, reexports, and transfers (in-country) to entities identified on the Entity List require licenses from BIS and are usually subject to a policy of denial. The availability of license exceptions in such transactions is very limited. The license review policy for each entity is identified in the license review policy column on the Entity List and the availability of license exceptions is noted in the **Federal Register** notices adding persons to the Entity List. BIS places entities on the Entity List based on certain sections of part 744 (Control Policy; End-User and End-Use Based) of the EAR.

The End-User Review Committee (ERC), composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy and, where appropriate, the Treasury, makes all decisions regarding additions to, removals from, or other modifications to

the Entity List. The ERC makes all decisions to add an entry to the Entity List by majority vote and all decisions to remove or modify an entry by unanimous vote. The Departments represented on the ERC approved this change to the Entity List.

Addition to the Entity List in This Rule

This rule implements the decision of the ERC to add one person to the Entity List on the basis of § 744.11 (License requirements that apply to entities acting contrary to the national security or foreign policy interests of the United States) of the EAR. The entry added to the Entity List consists of one person in Russia.

The ERC reviewed § 744.11(b) (Criteria for revising the Entity List) in making the determination to add this person to the Entity List. Under that paragraph, persons for whom there is reasonable cause to believe, based on specific and articulable facts, have been involved, are involved, or pose a significant risk of being or becoming involved in, activities that are contrary to the national security or foreign policy interests of the United States and those acting on behalf of such persons may be added to the Entity List. The person being added to the Entity List has been determined by the ERC to be involved in activities that are contrary to the national security or foreign policy interests of the United States. Those activities are described in Executive Order 13661 (79 FR 15533), *Blocking Property of Additional Persons Contributing to the Situation in Ukraine*, issued by the President on March 16, 2014. This Order expanded the scope of the national emergency declared in Executive Order 13660, finding that the actions and policies of the Government of the Russian Federation with respect to Ukraine—including the deployment of Russian Federation military forces in Crimea (Occupied)—undermine democratic processes and institutions in Ukraine; threaten its peace, security, stability, sovereignty, and territorial integrity; and contribute to the misappropriation of its assets, and thereby constitute an unusual and extraordinary threat to the national security and foreign policy of the United States.

Specifically, Executive Order 13661 includes a directive that all property and interests in property that are in the United States, that hereafter come within the United States, or that are or thereafter come within the possession or control of any United States person (including any foreign branch) of the following persons are blocked and may not be transferred, paid, exported,

withdrawn, or otherwise dealt in: Persons operating in the defense or related materiel sector in the Russian Federation. Under Section 8 of the Order, all agencies of the United States Government are directed to take all appropriate measures within their authority to carry out the provisions of the Order. The Department of the Treasury's Office of Foreign Assets Control, pursuant to Executive Order 13661, has designated the following person: United Shipbuilding Corporation. In conjunction with that designation, the Department of Commerce adds to the Entity List under this rule and imposes a license requirement for exports, reexports, or transfers (in-country) to this blocked person. This license requirement implements an appropriate measure within the authority of the EAR to carry out the provisions of Executive Order 13661.

The person added to the Entity List in this rule under Executive Order 13661 operates in the Russian Federation's defense or related materiel sector. United Shipbuilding Corporation is a Russian state-owned company that manufactures, among other things, ordnance and accessories, and is engaged in shipbuilding, repair, and maintenance. Therefore, pursuant to § 744.11 of the EAR, the conduct of this person raises sufficient concern that prior review of exports, reexports, or transfers (in-country) of items subject to the EAR involving this person, and the possible imposition of license conditions or license denials on shipments to these persons, will enhance BIS's ability to protect the foreign policy and national security interests of the United States.

For the person added to the Entity List, there is a license requirement for all items subject to the EAR and a license review policy of presumption of denial. The license requirements apply to any transaction in which items are to be exported, reexported, or transferred (in-country) to any of the persons or in which such persons act as purchaser, intermediate consignee, ultimate consignee, or end-user. In addition, no license exceptions are available for exports, reexports, or transfers (in-country) to the person being added to the Entity List in this rule.

This final rule adds the following person to the Entity List:

Russia

1. *United Shipbuilding Corporation*, a.k.a., the following four aliases:—Obedinennaya Sudostroitel'naya Korporatsiya OAO;

—OJSC United Shipbuilding Corporation; *and*
—United Shipbuilding Corporation Joint Stock Company; *and*
—OSK OAO.

90, Marata ul., St. Petersburg 191119, Russia; *and* 11, Sadovaya-Kudrinskaya str., Moscow 123242, Russia.

B. Change to the license requirements and review policy for Russia

This final rule makes the following additional changes to the EAR to implement changes to the license requirements and review policy for Russia.

Section 732.3 Steps Regarding the Ten General Prohibitions

In paragraph (d)(4), this rule adds Russia to the list of countries that are subject to other special controls provisions. Specifically, this paragraph indicates that the Commerce Country Chart in Supplement No. 1 to part 738 sets forth license requirements for Russia, and part 746 sets out additional license requirements. In paragraph (i), this rule also adds a sentence referencing § 746.5 for Russian Industry Sector Sanctions.

Supplement No. 1 to Part 738—Commerce Country Chart

This rule adds a new footnote 6 designation for Russia to alert members of the public to additional license requirements pursuant to § 746.5 Russian Industry Sector Sanctions for ECCNs 0A998, 1C992, 3A229, 3A231, 3A232, 6A991, 8A992, and 8D999.

Section 740.2 Restrictions on All License Exceptions

This rule revises § 740.2(a)(6) by adding restrictions on license exception eligibility when a license is required under limited sanctions for specified countries, unless a license exception or portion thereof is specifically listed in the license exceptions paragraph pertaining to a particular sanctioned country. Specifically, Russia (§ 746.5) is added. This change clarifies restrictions for license exceptions that are not specifically authorized to countries under limited sanctions in part 746, as well as implementing this restriction for the limited sanctions on Russia.

Section 742.4 National Security

This rule removes Russia's favorable license review status under national security reasons for control in § 742.4(b)(5). In light of recent actions by Russia and the sanctions that the U.S. and other countries are placing on Russia, this favorable license review status is removed. As a result of this

rule, Russia will no longer receive the enhanced favorable licensing treatment previously afforded to Russia under § 742.4(b)(5). Instead, the licensing policy for Russia will be the general licensing policy for countries in Country Group D:1 as set forth in § 742.4(b)(2). Kazakhstan and Mongolia will continue to receive enhanced favorable licensing treatment under § 742.4(b)(5).

Section 746.1 Introduction

This rule redesignates paragraph (c) as paragraph (d) and adds a new paragraph (c) to explain where to find the Russian Industry Sector Sanctions in part 746, as well as where these sanctions are referenced in the EAR.

Section 746.5 Russian Industry Sector Sanctions

This rule adds new § 746.5 entitled Russian Industry Sector Sanctions. This section imposes controls on the export, reexport or transfer (in-country) of any item subject to the EAR listed in Supplement No. 2 to this part and items specified in ECCNs 0A998, 1C992, 3A229, 3A231, 3A232, 6A991, 8A992, and 8D999 when the exporter, reexporter or transferor knows or is informed that the item will be used directly or indirectly in Russia's energy sector for exploration or production from deepwater (greater than 500 feet), Arctic offshore, or shale projects in Russia that have the potential to produce oil or gas or is unable to determine whether the item will be used in such projects in Russia.

Such items include, but are not limited to, drilling rigs, parts for horizontal drilling, drilling and completion equipment, subsea processing equipment, Arctic-capable marine equipment, wireline and down hole motors and equipment, drill pipe and casing, software for hydraulic fracturing, high pressure pumps, seismic acquisition equipment, remotely operated vehicles, compressors, expanders, valves, and risers. No license exceptions may overcome the license requirements set forth in § 746.5, except License Exception GOV § 740.11(b).

The license review policy for all items requiring a license for export to Russia is presumption of denial when there is potential for use directly or indirectly for exploration or production from deepwater (greater than 500 feet), Arctic offshore, or shale projects in Russia that have the potential to produce oil. To assist in the identification of such license applications, this rule indicates that license applications submitted to BIS under this section may include the phrase "section 746.5" in Block 9

(Special Purpose) in Supplement No. 1 to part 748.

Supplement No. 2 to Part 746—Russian Industry Sector Sanctions List

This rule adds Supplement No. 2 to Part 746 to a supplement that was previously reserved under the EAR. This new Supplement No. 2 identifies items that are subject to the new § 746.5 Russian Industry Sector Sanctions, in addition to the five ECCNs identified in that section. The items identified in new Supplement No. 2 are set forth as "Schedule B numbers." A Schedule B number is a 10-digit commodity classification number administered by the Census Bureau and is used for reporting foreign trade. The source for the Schedule B numbers and descriptions in this list is the Bureau of the Census's Schedule B concordance of exports 2014. Census's Schedule B List 2014 can be found at <http://www.census.gov/foreign-trade/schedules/b/2014/index.html>.

Supplement No. 1 to Part 774—Commerce Control List

ECCNs 1C992, 3A229, 3A231, 3A232, 6A991, and 8A992 are amended by revising the License Requirements sections to add a license requirement that applies to these ECCNs when destined to Russia pursuant to § 746.5 of the EAR.

ECCN 0A998 is added to control specific oil and gas exploration items, including software and data. Many U.S. companies are hired to provide or analyze seismic or other types of data in order to assist in oil exploration. This data does not come within the definition of "technology," as it does not pertain to the development, production or use of listed commodities or software, and is not specific information necessary for any of the following: Operation, installation, maintenance, repair, overhaul, refurbishing, or other terms specified in ECCNs on the CCL that control technology. However, this data product obtained through the analysis of raw seismic or other types of data is a commodity sold by companies. Such data is now controlled under this new entry. The Commerce Country Chart in Supplement No. 1 to part 738 is not designed to provide license requirements for this type of license requirement. In addition, BIS is making an exception to its general policy of not including software in A group ECCNs and is including oil and gas exploration software in ECCN 0A998. For more precise information about the license requirement and license review policy

under the Russian Industry Sector Sanctions, see § 746.5 of the EAR.

ECCN 8D999 is added to the Commerce Control List to control software specially designed for the operation of unmanned vessels used in the oil and gas industry of Russia. For more information about the license requirements and license review policy under the Russian Industry Sector Sanctions, see § 746.5 of the EAR.

No Savings Clause

Given the foreign policy objective of this rule, there is no savings clause in this rule. Accordingly, shipments of items removed from eligibility for a License Exception or export or reexport without a license (NLR) as a result of this regulatory action that were en route aboard a carrier to a port of export or reexport, on August 6, 2014, pursuant to actual orders for export or reexport to a foreign destination, may not proceed to that destination under the previous eligibility for a License Exception or export or reexport without a license (NLR).

Foreign Policy Report

The application of Russian Industry Sector Sanctions controls to the items covered by this rule imposes a foreign policy control. Section 6(f) of the Export Administration Act requires that a report be delivered to Congress before imposing such controls. The report was delivered to Congress on August 1, 2014.

Export Administration Act

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013) and as extended by the Notice of August 8, 2013, 78, 2013, 78 FR 49107 (August 12, 2013), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety

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

2. Notwithstanding any other provision of law, no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by OMB under control number 0694–0088, Simplified Network Application Processing System, which includes, among other things, license applications and carries a burden estimate of 43.8 minutes for a manual or electronic submission.

Total burden hours associated with the PRA and OMB control number 0694–0088 are not expected to increase as a result of this rule. You may send comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget (OMB), by email to Jasmeet.K.Seehra@omb.eop.gov, or by fax to (202) 395–7285.

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

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public comment and a delay in effective date are inapplicable because this regulation involves a military or foreign affairs function of the United States. (*See* 5 U.S.C. 553(a)(1)). BIS implements this rule to advance U.S. policy toward Russia and therefore protect U.S. national security or foreign policy interests by preventing items from being exported, reexported, or transferred (in country) to the person being added to the Entity List, and for use in Russia's energy sector intended for exploration or production from deepwater (greater than 500 feet), Arctic offshore, or shale projects that have the potential to produce oil. If this rule were delayed to allow for notice and comment and a delay in effective date, then the entity being added to the Entity List by this action would continue to be able to

receive items without a license and to conduct activities contrary to the national security or foreign policy interests of the United States. In addition, publishing a proposed rule would give this party notice of the U.S. Government's intention to place the person on the Entity List and would create an incentive for this person to either accelerate receiving items subject to the EAR to conduct activities that are contrary to the national security or foreign policy interests of the United States, and/or to take steps to set up additional aliases, change addresses, and other measures to try to limit the impact of the listing on the Entity List once a final rule was published. In addition, U.S. national security and foreign policy also would be undermined by not immediately restricting the export, reexport or transfer (in-country) of certain items related to the energy sector in Russia. Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

List of Subjects

15 CFR Parts 732 and 740

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 738

Exports.

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

15 CFR Part 746

Exports, Reporting and recordkeeping requirements.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements.

Accordingly, parts 732, 738, 740, 742, 744, 746 and 774 of the Export Administration Regulations (15 CFR parts 730–774) are amended as follows:

PART 732—[AMENDED]

■ 1. The authority citation for 15 CFR part 732 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

■ 2. Section 732.3 is amended:

- a. By revising paragraph (d)(4); and
- b. By revising paragraph (i) introductory text to read as follows:

§ 732.3 Steps regarding the ten general prohibitions.

* * * * *

(d) * * *

(4) Destinations subject to embargo and other special controls provisions. The Country Chart does not apply to Cuba, Iran, North Korea, and Syria. For those countries you should review the provisions at part 746 of the EAR and may skip this step concerning the Country Chart. For Iraq and Russia, the Country Chart provides for certain license requirements, and part 746 of the EAR provides additional requirements.

* * * * *

(i) *Step 14: Embargoed countries and special destinations.* If your destination for any item is Cuba, Iran, Iraq, North Korea, or Syria, you must consider the requirements of parts 742 and 746 of the EAR. Unless otherwise indicated, General Prohibition Six (Embargo) applies to all items subject to the EAR, i.e. both items on the CCL and within EAR99. See § 746.1(b) for destinations subject to limited sanctions under United Nations Security Council arms embargoes. See § 746.5 for Russian Industry Sector Sanctions. You may not make an export or reexport contrary to the provisions of part 746 of the EAR without a license unless:

* * * * *

PART 738—[AMENDED]

■ 3. The authority citation for 15 CFR part 738 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c; 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

■ 4. Supplement No. 1 to part 738 is amended by:

- a. Adding footnote designation “6” to “Russia”; and

■ b. Adding footnote 6 to read as follows:

Supplement No. 1 to Part 738—Commerce Country Chart

* * * * *

⁶ See § 746.5 for additional license requirements under the Russian Industry Sector Sanctions for ECCNs 0A998, 1C992, 3A229, 3A231, 3A232, 6A991, 8A992, and 8D999.

PART 740—[AMENDED]

■ 5. The authority citation for 15 CFR part 740 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 7201 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

■ 6. Section 740.2 is amended by revising paragraph (a)(6) to read as follows:

§ 740.2 Restrictions on all license exceptions.

(a) * * *

(6) The export or reexport is to a sanctioned destination (Cuba, Iran, North Korea, and Syria) or a license is required based on a limited sanction (Russia) unless a license exception or

portion thereof is specifically listed in the license exceptions paragraph pertaining to a particular sanctioned country in part 746 of the EAR.

* * * * *

PART 742—[AMENDED]

■ 7. The authority citation for 15 CFR part 742 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013); Notice of November 7, 2013, 78 FR 67289 (November 12, 2013).

■ 8. Section 742.4(b)(5) is amended to read as follows:

§ 742.4 National security.

* * * * *

(b) * * *

(5) In recognition of efforts made to adopt safeguard measures for exports and reexports, Kazakhstan and Mongolia are accorded enhanced

favorable consideration licensing treatment.

* * * * *

PART 744—[AMENDED]

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

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013); Notice of September 18, 2013, 78 FR 58151 (September 20, 2013); Notice of November 7, 2013, 78 FR 67289 (November 12, 2013); Notice of January 21, 2014, 79 FR 3721 (January 22, 2014).

■ 10. Supplement No. 4 to part 744 is amended by adding under Russia, in alphabetical order, one Russian entity.

The addition reads as follows:

Supplement No. 4 to Part 744—Entity List

Country	Entity	License requirement	License review policy	Federal Register citation
* * * * *				
Russia				
* * * * *				
	United Shipbuilding Corporation, a.k.a., the following four aliases: —Obedinennaya Sudostroitel'naya Korporatsiya OAO; and —OJSC United Shipbuilding Corporation; and —United Shipbuilding Corporation Joint Stock Company; and —OSK OAO. 90, Marata ul., St. Petersburg 191119, Russia; and 11, Sadovaya-Kudrinskaya str., Moscow 123242, Russia.	For all items subject to the EAR. (See § 744.11 of the EAR).	Presumption of denial	79 FR [INSERT FR PAGE NUMBER] 8/6/14
* * * * *				

PART 746—[AMENDED]

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

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 287c; Sec 1503, Pub. L. 108–11, 117 Stat. 559; 22 U.S.C. 6004; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 614; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338, 69 FR

26751, 3 CFR, 2004 Comp., p 168; Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Presidential Determination 2007–7 of December 7, 2006, 72 FR 1899 (January 16, 2007); Notice of August 8, 2013, 78 FR 49107 (August 12, 2013); Notice of May 7, 2014, 79 FR 26589 (May 9, 2014).

■ 12. Section 746.1 is amended by redesignating paragraph (c) as (d) and adding a new paragraph (c) to read as follows.

§ 746.1 Introduction.

* * * * *

(c) *Russian Industry Sector Sanctions.* The Russian Industry Sector Sanctions are set forth under § 746.5 and referenced under the License Requirements section of certain Export Control Classification Numbers (ECCNs) in Supplement No. 1 to part 774 (Commerce Control List), as well as in

a footnote to the Commerce Country Chart in Supplement No. 1 to part 738.

* * * * *

■ 13. Add § 746.5 to read as follows:

§ 746.5 Russian Industry Sector Sanctions.

(a) *License requirements.* (1) *General prohibition.* As authorized by Section 6 of the Export Administration Act of 1979, a license is required to export, reexport or transfer (in-country) any item subject to the EAR listed in Supplement No. 2 to this part and items specified in ECCNs 0A998, 1C992, 3A229, 3A231, 3A232, 6A991, 8A992, and 8D999 when you know that the item will be used directly or indirectly in exploration for, or production of, oil or gas in Russian deepwater (greater than 500 feet) or Arctic offshore locations or shale formations in Russia, or are unable to determine whether the item will be used in such projects. Such items include, but are not limited to, drilling rigs, parts for horizontal drilling, drilling and completion equipment, subsea processing equipment, Arctic-capable marine equipment, wireline and down hole motors and equipment, drill pipe and casing, software for hydraulic fracturing, high pressure pumps, seismic acquisition equipment, remotely operated vehicles, compressors,

expanders, valves, and risers. You should be aware that other provisions of the EAR, including parts 742 and 744, also apply to exports and reexports to Russia. License applications submitted to BIS under this section may include the phrase “section 746.5” in Block 9 (Special Purpose) in Supplement No. 1 to part 748.

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

(b) *Licensing policy.* Applications for the export, reexport or transfer (in-

country) of any item that requires a license for Russia will be reviewed with a presumption of denial when for use directly or indirectly for exploration or production from deepwater (greater than 500 feet), Arctic offshore, or shale projects in Russia that have the potential to produce oil.

(c) *License exceptions.* No license exceptions may overcome the license requirements set forth in this section, except License Exception GOV (§ 740.11(b)).

■ 14. Supplement No. 2 to part 746 is added to read as follows:

Supplement No. 2 to Part 746—Russian Industry Sector Sanction List

The source for the Schedule B numbers and descriptions in this list comes from the Bureau of the Census’s Schedule B concordance of exports 2014. Census’s Schedule B List 2014 can be found at <http://www.census.gov/foreign-trade/schedules/b/2014/index.html> The Introduction Chapter of the Schedule B provides important information about classifying products and interpretations of the Schedule B, e.g., NESOI means Not Elsewhere Specified or Included. In addition, important information about products within a particular chapter may be found at the beginning of chapters.

Schedule B	Description
7304110000	LINE PIPE OF A KIND USED FOR OIL OR GAS PIPELINES, SEAMLESS, OF STAINLESS STEEL
7304191020	LINE PIPE OF A KIND USED FOR OIL OR GAS PIPELINES, SEAMLESS, OF IRON (NONCAST) OR NONALLOY STEEL, WITH AN OUTSIDE DIAMETER NOT EXCEEDING 114.3 MM
7304191050	LINE PIPE FOR OIL OR GAS PIPELINES, SEAMLESS, IRON (NONCAST) OR NONALLOY STEEL, WITH OUTSIDE DIAMETER OVER 114.3 MM BUT NOT OVER 406.4 MM
7304191080	LINE PIPE OF A KIND USED FOR OIL OR GAS PIPELINES, SEAMLESS, OF IRON (NONCAST) OR NONALLOY STEEL, WITH AN OUTSIDE DIAMETER EXCEEDING 406.4 MM
7304195020	LINE PIPE OF A KIND USED FOR OIL OR GAS PIPELINES, SEAMLESS, OF OTHER ALLOY STEEL, NOT STAINLESS, WITH AN OUTSIDE DIAMETER NOT EXCEEDING 114.3 MM
7304195050	LINE PIPE, USED FOR OIL OR GAS PIPELINES, SEAMLESS, OF OTHER ALLOY STEEL, NOT STAINLESS, WITH AN OUTSIDE DIAMETER >114.3 MM, BUT <406.4 MM
7304195080	LINE PIPE OF A KIND USED FOR OIL OR GAS PIPELINES, SEAMLESS, OF ALLOY STEEL, NOT STAINLESS, WITH AN OUTSIDE DIAMETER EXCEEDING 406.4 MM
7304220000	OIL WELL DRILL PIPE, OF STAINLESS STEEL
7304233000	OIL WELL DRILL PIPE, OF IRON OR NONALLOY STEEL
7304236000	OIL WELL DRILL PIPE, OF ALLOY STEEL OTHER THAN STAINLESS STEEL
7304241000	OIL WELL CASING OF STAINLESS STEEL
7304246000	OIL WELL TUBING OF STAINLESS STEEL
7304291055	OIL WELL CASING OF IRON OR NONALLOY STEEL
7304293155	OIL WELL CASING OF OTHER ALLOY STEEL NOT STAINLESS
7304295000	OIL WELL TUBING OF IRON OR NONALLOY STEEL
7304296100	OIL WELL TUBING OF OTHER ALLOY STEEL OTHER THAN STAINLESS STEEL
7305111000	LINE PIPE FOR OIL OR GAS, LONGITUDINALLY SUBMERGED ARC WELDED, EXTERNAL DIAMETER MORE THAN 406.4 MM, CIRCULAR CROSS-SECTIONS, OF IRON OR NONALLOY STEEL
7305115000	LINE PIPE FOR OIL/GAS PIPELINES, LONGITUDINALLY SUBMERGED ARC WELDED WITH EXTERNAL DIAMETER OVER 406.4 MM, OF ALLOY STEEL, WITH CIRCULAR CROSS-SECTION
7305121000	LINE PIPE FOR OIL OR GAS, OTHER LONGITUDINALLY WELDED, EXTERNAL DIAMETER MORE THAN 406.4 MM, CIRCULAR CROSS-SECTION, IRON OR NONALLOY STEEL
7305125000	LINE PIPE FOR OIL OR GAS PIPELINES, LONGITUDINALLY WELDED WITH EXTERNAL DIAMETER >406.4 MM, OF ALLOY STEEL, WITH CIRCULAR CROSS SECTION
7305191000	LINE PIPE FOR OIL OR GAS OTHER THAN LONGITUDINALLY WELDED, EXTERNAL DIAMETER MORE THAN 406.4 MM, CIRCULAR CROSS-SECTION, IRON OR NONALLOY STEEL
7305195000	LINE PIPE FOR OIL OR GAS PIPELINES, WITH EXTERNAL DIAMETER >406.4 MM, OF ALLOY STEEL, CIRCULAR CROSS SECTION, WELDED/RIVETED, NESOI

Schedule B	Description
7305203000	CASING, OIL OR GAS DRILLING, OTHER THAN SEAMLESS, CIRCULAR CROSS-SECTION, EXTERNAL DIAMETER OVER 406.4 MM, IRON OR NONALLOY STEEL
7305207000	CASING, OIL OR GAS DRILLING, OTHER THAN SEAMLESS, CIRCULAR CROSS-SECTION, EXTERNAL DIAMETER OVER 406.4 MM, ALLOY STEEL
7306110000	LINE PIPE FOR OIL OR GAS NOT SEAMLESS NESOI, OF STAINLESS STEEL
7306191000	LINE PIPE FOR OIL OR GAS NOT SEAMLESS NESOI, OF IRON OR NONALLOY STEEL
7306195000	LINE PIPE FOR OIL OR GAS NOT SEAMLESS NESOI, OF ALLOY STEEL OTHER THAN STAINLESS STEEL
7311000000	CONTAINERS FOR COMPRESSED OR LIQUEFIED GAS OF IRON OR STEEL
7613000000	ALUMINUM CONTAINERS FOR COMPRESSED OR LIQUEFIED GAS
8207130000	ROCK DRILLING OR EARTH BORING TOOLS WITH WORKING PART OF CERMENTS, AND PARTS THEREOF
8207191030	PERCUSSION ROCK DRILL BITS, CORE BITS AND REAMERS, OF BASE METAL, AND PARTS THEREOF
8207192030	ROTARY ROCK DRILL BITS, CORE BITS AND REAMERS OF BASE METAL, AND PARTS THEREOF
8207195030	ROCK DRILLING OR EARTH BORING TOOLS OF BASE METALS, NESOI, AND PARTS THEREOF
8413500010	OIL WELL AND OIL FIELD PUMPS, RECIPROCATING POSITIVE DISPLACEMENT
8413600050	OIL WELL AND OIL FIELD PUMPS, ROTARY POSITIVE DISPLACEMENT
8413820000	LIQUID ELEVATORS
8413920000	PARTS OF LIQUID ELEVATORS
8421398020	ELECTROSTATIC PRECIPITATORS, INDUSTRIAL GAS CLEANING EQUIPMENT
8421398030	INDUSTRIAL GAS CLEANING EQUIPMENT, NESOI
8421398040	GAS SEPARATION EQUIPMENT
8430494000	OFFSHORE OIL AND NATURAL GAS DRILLING AND PRODUCTION PLATFORMS
8430498010	BORING OR SINKING MACHINERY, ROTARY, FOR OIL WELL AND GAS FIELD DRILLING
8430498020	BORING OR SINKING MACHINERY FOR OIL WELL AND GAS FIELD DRILLING, NESOI
8431390050	PARTS SUITABLE FOR USE SOLELY OR PRINCIPALLY WITH THE OIL AND GAS FIELD MACHINERY OF HEADINGS 8425 TO 8430
8431434000	OFFSHORE OIL AND NATURAL GAS DRILLING AND PRODUCTION PLATFORM PARTS, OF SUBHEADING 8430.41 OR 8430.49
8431438010	PARTS OF OIL AND GAS FIELD MACHINERY OF SUBHEADING 8430.49 EXCEPT PARTS OF OFFSHORE DRILLING AND PRODUCTION PLATFORMS
8431438090	PARTS OF BORING OR SINKING MACHINERY OF SUBHEADING 8430.41 OR 8430.49, NESOI
8479899850	OIL AND GAS FIELD WIRE LINE AND DOWNHOLE EQUIPMENT
8705200000	MOBILE DRILLING DERRICKS
8708998175	PARTS AND ACCESSORIES, FOR MOTOR VEHICLES OF HEADING 8705.20, NESOI
8905200000	FLOATING OR SUBMERSIBLE DRILLING OR PRODUCTION PLATFORMS
8905901000	FLOATING DOCKS

■ 15. Reserved Supplement No. 3 to Part 746 is removed.

PART 774—[AMENDED]

■ 16. The authority citation for 15 CFR part 774 continues to read as follows:

Authority: 50 U.S.C. app. 2401 et seq.; 50 U.S.C. 1701 et seq.; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c; 22 U.S.C. 3201 et seq.; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 et seq.; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

■ 17. Supplement No. 1 to Part 774, Category 0, ECCN 0A998 is added after 0A988 to read as follows:

Supplement No. 1 to Part 774—The Commerce Control List

* * * * *

0A998 Oil and gas exploration equipment, software, and data, as follows (see List of Items Controlled).

License Requirements

Reason for Control: Foreign policy

Control(s):

Russian industry sector sanction applies to entire entry.

Country chart

See § 746.5 for specific license requirements and license review policy.

List Based License Exceptions (See Part 740 for a description of all license exceptions)

LVS: N/A
GBS: N/A
CIV: N/A

List of Items Controlled

Related Controls: N/A

Related Definitions: N/A

Items:

- a. Oil and gas exploration data, e.g., seismic analysis data.
- b. Hydraulic fracturing items, as follows:
 - b.1. Hydraulic fracturing design and analysis software and data.
 - b.2. Hydraulic fracturing 'proppant,' 'fracking fluid,' and chemical additives therefor.

Technical Note: A 'proppant' is a solid material, typically treated sand or man-made ceramic materials, designed to keep an induced hydraulic fracture open, during or following a fracturing treatment. It is added to a 'fracking fluid' which may vary in composition depending on the type of fracturing used, and can be gel, foam or slickwater-based.

b.3. High pressure pumps.

* * * * *

■ 18. Supplement No. 1 to part 774, Category 1, ECCN 1C992 is amended by revising the License Requirements section to read as follows:

1C992 Commercial charges and devices containing energetic materials, n.e.s. and nitrogen trifluoride in a gaseous state (see List of Items Controlled).

License Requirements

Reason for Control: AT, RS

Country chart (see Supp. No. 1 to part 738)

Control(s)

AT applies to entire entry.

AT Column 1

<i>Control(s)</i>		<i>Country chart (see Supp. No. 1 to part 738)</i>		<i>Control(s)</i>		<i>Country chart (see Supp. No. 1 to part 738)</i>		<i>License Requirements</i>		<i>Reason for Control: AT, UN</i>	
RS applies to entire entry.		A license is required for items controlled by this entry for export or reexport to Iraq and transfer within Iraq for regional stability reasons. The Commerce Country Chart is not designed to determine RS license requirements for this entry. See §§ 742.6 and 746.3 of the EAR for additional information.		Russian industry sector sanctions apply to entire entry.		See § 746.5 for specific license requirements and license review policy.		<i>Control(s)</i>		<i>Country chart (see Supp. No. 1 to part 738)</i>	
* * * *		* * * *		* * * *		* * * *		AT applies to entire entry.		AT Column 1	
■ 19. Supplement No. 1 to part 774, Category 3, ECCN 3A229 is amended by revising the License Requirements section to read as follows:		■ 21. Supplement No. 1 to part 774, Category 3, ECCN 3A232 is amended by revising the License Requirements section to read as follows:		■ 22. Supplement No. 1 to part 774, Category 6, ECCN 6A991 is amended by revising the License Requirements section to read as follows:		■ 23. Supplement No. 1 to part 774, Category 8, ECCN 8A992 is amended by revising the License Requirements section to read as follows:		UN applies to 8A992.I and m.		See § 746.1(b) for UN controls.	
3A229 Firing sets and equivalent high-current pulse generators (for detonators controlled by 3A232), as follows (see List of Items Controlled).		3A232 Detonators and multipoint initiation systems, as follows (see List of Items Controlled).		6A991 Marine or terrestrial acoustic equipment, n.e.s., capable of detecting or locating underwater objects or features or positioning surface vessels or underwater vehicles; and “specially designed” “parts” and “components,” n.e.s.		8A992 Vessels, marine systems or equipment, not controlled by 8A001 or 8A002, and “specially designed” “parts” and “components” therefor, and marine boilers and “parts,” “components,” “accessories,” and “attachments” therefor (see List of Items Controlled).		Russian industry sector sanctions apply to entire entry.		See § 746.5 for specific license requirements and license review policy.	
* * * *		* * * *		* * * *		* * * *		* * * *		* * * *	
License Requirements		License Requirements		License Requirements		License Requirements		* * * *		■ 24. Supplement No. 1 to part 774, Category 8, ECCN 8D999 is added after ECCN 8D992 to read as follows:	
Reason for Control: NP, AT		Reason for Control: AT, RS		Reason for Control: AT		Reason for Control: AT		Reason for Control: N/A		8D999 “Software” “specially designed” for the operation of unmanned submersible vehicles used in the oil and gas industry.	
<i>Control(s)</i>		<i>Country chart (see Supp. No. 1 to part 738)</i>		<i>Control(s)</i>		<i>Country chart (see Supp. No. 1 to part 738)</i>		<i>Control(s)</i>		<i>Country chart (see Supp. No. 1 to part 738)</i>	
NP applies to entire entry.		NP Column 1		AT applies to entire entry.		AT Column 1		Russian industry sector sanctions apply to entire entry.		See § 746.5 for specific license requirements and license review policy.	
AT applies to entire entry.		AT Column 1		Russian industry sector sanctions apply to entire entry.		See § 746.5 for specific license requirements and license review policy.		* * * *		List Based License Exceptions (See Part 740 for a description of all license exceptions)	
Russian industry sector sanctions apply to entire entry.		See § 746.5 for specific license requirements and license review policy.		* * * *		* * * *		CIV: N/A		TSR: N/A	
* * * *		* * * *		* * * *		* * * *		List of Items Controlled		Related Controls: N/A	
■ 20. Supplement No. 1 to part 774, Category 3, ECCN 3A231 is amended by revising the License Requirements section to read as follows:		■ 20. Supplement No. 1 to part 774, Category 3, ECCN 3A231 is amended by revising the License Requirements section to read as follows:		■ 20. Supplement No. 1 to part 774, Category 3, ECCN 3A231 is amended by revising the License Requirements section to read as follows:		■ 20. Supplement No. 1 to part 774, Category 3, ECCN 3A231 is amended by revising the License Requirements section to read as follows:		Related Definitions: N/A		Items:	
3A231 Neutron generator systems, including tubes, having both of the following characteristics (see List of Items Controlled).		3A231 Neutron generator systems, including tubes, having both of the following characteristics (see List of Items Controlled).		3A231 Neutron generator systems, including tubes, having both of the following characteristics (see List of Items Controlled).		3A231 Neutron generator systems, including tubes, having both of the following characteristics (see List of Items Controlled).		The list of items controlled is contained in the ECCN heading.		* * * *	
* * * *		* * * *		* * * *		* * * *		Dated: August 1, 2014.		Eric L. Hirschhorn,	
License Requirements		License Requirements		License Requirements		License Requirements		Under Secretary of Commerce for Industry and Security.		[FR Doc. 2014–18579 Filed 8–1–14; 4:15 pm]	
Reason for Control: NP, AT		Reason for Control: NP, AT		Reason for Control: NP, AT		Reason for Control: NP, AT		BILLING CODE 3510–33–P		DEPARTMENT OF THE TREASURY	
<i>Control(s)</i>		<i>Country chart (see Supp. No. 1 to part 738)</i>		<i>Control(s)</i>		<i>Country chart (see Supp. No. 1 to part 738)</i>		Internal Revenue Service		26 CFR Part 1	
NP applies to entire entry.		NP Column 1		AT applies to entire entry.		AT Column 2		[TD 9673]		RIN 1545–BK23	
AT applies to entire entry.		AT Column 1		Russian industry sector sanctions apply to entire entry.		See § 746.5 for specific license requirements and license review policy.		Longevity Annuity Contracts; Correction		AGENCY: Internal Revenue Service (IRS), Treasury.	
* * * *		* * * *		* * * *		* * * *		ACTION: Correcting amendment.			

SUMMARY: This document contains corrections to final regulations (TD 9673) that were published in the **Federal Register** on Wednesday, July 2, 2014 (79 FR 37633). The final regulations are relating to the use of longevity annuity contracts in tax qualified defined contribution plans.

DATES: This correction is effective August 6, 2014 and applicable beginning July 2, 2014.

FOR FURTHER INFORMATION CONTACT: Jamie Dvoretzky, at (202) 317-6799 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9673) that are the subject of this correction is under section 401(a) of the Internal Revenue Code.

Need for Correction

As published, the final (TD 9673) contains errors that may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.401(a)(9)–6 is corrected by revising paragraph (c)(4)(i) introductory text, the second sentence of paragraph (d)(1)(ii)(B), and paragraph (d)(3)(i) to read as follows:

§ 1.401(a)(9)–6 Required minimum distributions for defined benefit plans and annuity contracts.

* * * * *

(c) * * *

(4) * * *

(i) * * * In lieu of a life annuity payable to a designated beneficiary under paragraph (c)(1) or (2) of this A–17, a QLAC is permitted to provide for a benefit to be paid to a beneficiary after the death of the employee in an amount equal to excess of—

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(B) * * * If the excess premium (including the fair market value of an

annuity contract that is not intended to be a QLAC, if applicable) is returned to the non-QLAC portion of the employee's account after the last valuation date for the calendar year in which the excess premium was originally paid, then the employee's account balance for that calendar year must be increased to reflect that excess premium in the same manner as an employee's account balance is increased under A–2 of § 1.401(a)(9)–7 to reflect a rollover received after the last valuation date.

* * * * *

(3) * * *

(i) *Structural deficiency.* If a contract fails to be a QLAC at any time for a reason other than an excess premium described in paragraph (d)(1)(ii) of this A–17, then as of the date of purchase the contract will not be treated as a QLAC (for purposes of A–3(d) of § 1.401(a)(9)–5) or as a contract that is intended to be a QLAC (for purposes of paragraph (b) of this A–17).

* * * * *

Martin V. Franks,

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

[FR Doc. 2014–18547 Filed 8–5–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9673]

RIN 1545–BK23

Longevity Annuity Contracts; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations; correction.

SUMMARY: This document contains corrections to final regulations (TD 9673) that were published in the **Federal Register** on Wednesday, July 2, 2014 (79 FR 37633). The final regulations are relating to the use of longevity annuity contracts in tax qualified defined contribution plans. **DATES:** This correction is effective August 6, 2014 and applicable beginning July 2, 2014.

FOR FURTHER INFORMATION CONTACT: Jamie Dvoretzky, at (202) 317–6799 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9673) that are the subject of this correction is

under section 401(a) of the Internal Revenue Code.

Need for Correction

As published, the final regulations (TD 9673) contain errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the final regulations (TD 9673), that are the subject of FR Doc. 2014–15524, are corrected as follows:

1. On page 37634, third column, in the preamble, first line from the top of the page, the language “premium payments will be taken into” is corrected to read “premium payments would be taken into”.

2. On page 37636, first column, in the footnotes, the seventh line from the bottom of the page, the language “411(a) of the Code). Section 205(e)(2) of the” is corrected to read “411(a)). Section 205(e)(2) of the”.

3. On page 37637, first column, in the preamble, under the paragraph heading “II. IRAs”, the first sentence is removed.

Martin V. Franks,

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

[FR Doc. 2014–18558 Filed 8–5–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 943

[SATS No. TX–066–FOR; Docket ID: OSM–2014–0001; S1D1SSS08011000SX066A0006 7F144S180110; S2D2SSS08011000SX0 66A00033F14XS501520]

Texas Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are approving an amendment to the Texas regulatory program (Texas program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Texas proposed revisions to its regulations regarding annual permit fees. Texas revised its program at its own initiative to raise revenues sufficient to cover its anticipated share of costs to administer the coal regulatory program and to encourage mining companies to more quickly reclaim lands and request bond

release, thereby fulfilling SMCRA's purpose of assuring the reclamation of mined land as quickly as possible.

DATES: Effective August 6, 2014.

FOR FURTHER INFORMATION CONTACT: Elaine Ramsey, Director, Tulsa Field Office. Telephone: (918) 581-6430. Email: eramsey@osmre.gov.

SUPPLEMENTARY INFORMATION:

- I. Background on the Texas Program
- II. Submission of the Amendment
- III. OSMRE's Findings
- IV. Summary and Disposition of Comments
- V. OSMRE's Decision
- VI. Procedural Determinations

I. Background on the Texas Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, "a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act . . . ; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act." See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Texas program effective February 16, 1980. You can find background information on the Texas program, including the Secretary's findings, the disposition of comments, and the conditions of approval, in the February 27, 1980, **Federal Register** (45 FR 13008). You can find later actions on the Texas program at 30 CFR 943.10, 943.15, and 943.16.

II. Submission of the Amendment

By letter dated December 19, 2013 (Administrative Record No. TX-703), and on their own initiative, Texas sent us an amendment to its program under SMCRA (30 U.S.C. 1201 et seq.). We announced receipt of the proposed amendment in the March 10, 2014, **Federal Register** (79 FR 13264). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. We did not hold a public hearing or meeting, because no one requested one. The public comment period ended on April 10, 2014. We did not receive any public comments.

III. OSMRE's Findings

The following are the findings we made concerning the amendment under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17. We are

approving the amendment as described below.

16 Texas Administrative Code (TAC) Section 12.108 Permit Fees

Texas proposed to revise its regulations at 16 TAC Sections 12.108(b)(1)–(3), adjusting the annual coal mining permit fees for calendar years 2013 and 2014. Fees for mining activities during calendar year 2013 must be paid by coal mine operations by March 15, 2014, which is in Texas' 2014 fiscal year. Similarly, fees for mining activities during calendar year 2014 are due by March 15, 2015, which is in Texas' 2015 fiscal year.

By this amendment, Texas is:

(1) Decreasing the current fee in paragraph (b)(1) from \$154.00 to \$84.00 for each acre of land within the permit area on which coal or lignite was actually removed during the calendar year;

(2) Increasing the current fee in paragraph (b)(2) from \$10.40 to \$12.00 for each acre of land within a permit area covered by a reclamation bond on December 31st of the year; and

(3) Decreasing the current fee in paragraph (b)(3) from \$6,900.00 to \$6,540.00 for each permit in effect on December 31st of the year.

The Federal regulations at 30 CFR 777.17 provide that applications for surface coal mining permits must be accompanied by a fee determined by the regulatory authority. The Federal regulations also provide that the fees may be less than, but not more than, the actual or anticipated cost of reviewing, administering, and enforcing the permit.

Texas' amendment describes how its coal mining regulatory program is funded. Texas operates on a biennial budget which appropriates general revenue funds for permitting and inspecting coal mining facilities within the State. This appropriation is contingent on the Railroad Commission of Texas (Commission) assessing fees sufficient to generate revenue to recover the general revenue appropriation. When calculating anticipated costs to the Commission for regulating coal mining activity, Texas anticipates OSMRE will provide some grant funding for regulatory program costs based on Section 705(a) of SMCRA. Texas has estimated that annual fees at the revised amounts in this amendment will result in revenue that, when coupled with permit application fees, is expected to provide for more than 50 percent of the anticipated regulatory program costs during each year of the biennium. OSMRE agrees that this is a reasonable expectation in light of the Administration's proposed fiscal year

2015 budget which reduces overall funding to states and may result in them receiving less than fifty percent of their anticipated regulatory program costs.

Texas adjusts its fees biennially to recover the amounts expended from state appropriations in accordance with a formula and schedule agreed to in 2005 by the coal mining industry and the Commission. This amendment represents the fifth adjustment to surface mining fees based upon that agreement.

We find that Texas' fee changes are consistent with the discretionary authority provided by the Federal regulation at 30 CFR 777.17. Therefore, OSMRE approves Texas' proposed permit fees, recognizing that Texas has a process to adjust its fees to cover the cost of its regulatory program not covered by the Federal grant.

IV. Summary and Disposition of Comments

Public Comments

We asked for public comments on the amendment, but did not receive any.

Federal Agency Comments

On January 9, 2014, pursuant to 30 CFR 732.17(h)(11)(i) and Section 503(b) of SMCRA, we requested comments on the amendment from various Federal agencies with an actual or potential interest in the Texas program (Administrative Record No. TX-703.01). We did not receive any comments.

Environmental Protection Agency (EPA) Concurrence and Comment

Under 30 CFR 732.17(h)(11)(ii), we are required to get written concurrence from EPA for those provisions of the program amendment that relate to air or water quality standards issued under the authority of the Clean Water Act (33 U.S.C. 1251 et seq.) or the Clean Air Act (42 U.S.C. 7401 et seq.). None of the revisions that Texas proposed to make in this amendment pertain to air or water quality standards. Therefore, we did not ask EPA to concur on the amendment. However, on January 9, 2014, under 30 CFR 732.17(h)(11)(i), we requested comments from the EPA on the amendment (Administrative Record No. TX-703.1). The EPA did not respond to our request.

State Historical Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP)

Under 30 CFR 732.17(h)(4), we are required to request comments from the SHPO and ACHP on amendments that may have an effect on historic properties. On January 9, 2014, we requested comments on Texas'

amendment (Administrative Record No. TX-703.01), but neither the SHPO nor ACHP responded to our request.

V. OSMRE's Decision

Based on the above findings, we approve the amendment Texas submitted to the OSMRE on December 19, 2013 (Administrative Record No. TX-703).

To implement this decision, we are amending the Federal regulations at 30 CFR Part 943 that codify decisions concerning the Texas program. We find that good cause exists under 5 U.S.C. 553(d)(3) to make this final rule effective immediately. Section 503(a) of SMCRA requires that the State's program demonstrate that it has the capability of carrying out the provisions of the Act and meeting its purposes. Making this rule effective immediately will expedite that process. SMCRA requires consistency of state and Federal standards.

VI. Procedural Determinations

Executive Order 12630—Taking

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulation.

Executive Order 12866—Regulatory Planning and Review

This rule is exempt from review by the Office of Management and Budget (OMB) under Executive Order 12866.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by Section 3 of Executive Order 12988 and has determined that this rule meets the applicable standards of Subsections (a) and (b) of that Section. However, these standards are not applicable to the actual language of state regulatory programs and program amendments, because each program is drafted and promulgated by a specific state, not by OSMRE. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed state regulatory programs and program amendments submitted by the states must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

Executive Order 13132—Federalism

This rule does not have Federalism implications. SMCRA delineates the

roles of the Federal and state governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to "establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations." Section 503(a)(1) of SMCRA requires that state laws regulating surface coal mining and reclamation operations be "in accordance with" the requirements of SMCRA, and Section 503(a)(7) requires that state programs contain rules and regulations "consistent with" regulations issued by the Secretary pursuant to SMCRA.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on Federally-recognized Indian tribes and have determined that the rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. The basis for this determination is that our decision is on a State regulatory program and does not involve Federal regulations involving Indian lands.

Executive Order 13211—Regulations That Significantly Affect the Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211, which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

This rule does not require an environmental impact statement because Section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of Section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 et seq.).

Regulatory Flexibility Act

The Department of the Interior certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). The State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) Does not have an annual effect on the economy of \$100 million; (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, state, or local government agencies, or geographic regions; and (c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

Unfunded Mandates

This rule will not impose an unfunded mandate on state, local, or tribal governments or the private sector of \$100 million or more in any given year. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation did not impose an unfunded mandate.

List of Subjects in 30 CFR Part 943

Intergovernmental relations, Surface mining.

Dated: May 28, 2014.

Ervin J. Barchenger,

Regional Director, Mid-Continent Region.

For the reasons set out in the preamble, 30 CFR Part 943 is amended as set forth below:

PART 943—TEXAS

■ 1. The authority citation for Part 943 continues to read as follows:

Authority: 30 U.S.C. 1201 et seq.

■ 2. Section 943.15 is amended in the table by adding a new entry in chronological order by “Date of final publication” to read as follows:

§ 943.15 Approval of Texas regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/Description
* * * * *	* * * * *	* * * * *
December 19, 2013	August 6, 2014	16 TAC 12.108(b)(1)–(3).

[FR Doc. 2014–18643 Filed 8–5–14; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165**

[Docket No. USCG–2014–0722]

Safety Zones; Recurring Events in Captain of the Port Duluth Zone—Superior Man Triathlon

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce its safety zone for the Superior Man Triathlon in Duluth, MN from 6 a.m. through 9 a.m. on August 24, 2014. This action is necessary to protect participants during the swimming portion of the Superior Man Triathlon. During the enforcement period, entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Duluth or his designated on-scene representative.

DATES: The regulations in 33 CFR 165.943(b) will be enforced from 6 a.m. through 9 a.m. on August 24, 2014, for the Superior Man Triathlon safety zone, § 165.943(a)(8).

FOR FURTHER INFORMATION CONTACT: If you have questions on this document, call or email LT Judson Coleman, Chief of Waterways Management, Coast Guard; telephone (218) 725–3818, email Judson.A.Coleman@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone for the annual Superior Man Triathlon in 33 CFR 165.943(a)(8) from 6 a.m. through 9 a.m. on August 24, 2014 on all waters of the Duluth Harbor Basin,

Northern Section, including the Duluth Entry encompassed in an imaginary line beginning at point 46°46′36.12″ N 092°06′06.99″ W, running southeast to 46°46′32.75″ N 092°06′01.74″ W, running northeast to 46°46′45.92″ N 092°05′45.18″ W, running northwest to 46°46′49.47″ N 092°05′49.35″ W and finally running southwest back to the starting point.

Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Duluth or his designated on-scene representative. The Captain of the Port’s designated on-scene representative may be contacted via VHF Channel 16.

This document is issued under authority of 33 CFR 165.943 and 5 U.S.C. 552(a). In addition to this publication in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of the enforcement of this safety zone via Broadcast Notice to Mariners. The Captain of the Port Duluth or his on-scene representative may be contacted via VHF Channel 16.

Dated: July 21, 2014.

A.H. Moore, Jr.,

Commander, U.S. Coast Guard, Captain of the Port Duluth.

[FR Doc. 2014–18601 Filed 8–5–14; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165**

[Docket Number USCG–2014–0635]

Safety Zone; Gay Games 9 Open Water Swim, Lake Erie, Edgewater Park, Cleveland, OH

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on Lake Erie, Edgewater Park, Cleveland, OH, for an open water swim event. This temporary safety zone is necessary to protect swimmers from vessels operating in the area. This safety zone will restrict vessels from a portion of Lake Erie during the Gay Games 9 Open Water swimming event.

DATES: This temporary final rule is effective from 8 a.m. until 1 p.m. on August 10, 2014.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2014–0635]. To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket number in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LTJG Amanda Cost, Chief of Waterways Management, U.S. Coast Guard Sector Buffalo; telephone 716–843–9343, email SectorBuffaloMarineSafety@uscg.mil. If you have questions on viewing the docket, call Ms. Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826 or 1–800–647–5527.

SUPPLEMENTARY INFORMATION:**Table of Acronyms**

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking
TFR Temporary Final Rule

A. Regulatory History and Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable and contrary to the public interest. The final details for this event were not known to the Coast Guard until there was insufficient time remaining before the event to publish an NPRM. Thus, delaying the effective date of this rule to wait for a comment period to run would be both impracticable and contrary to the public interest because it would inhibit the Coast Guard’s ability to protect spectators and vessels from the hazards associated with a maritime fireworks display, which is discussed further below.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this temporary rule effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed in the preceding paragraph, waiting for a 30 day notice period to run would be impracticable and contrary to the public interest.

B. Basis and Purpose

Between 8 a.m. and 1 p.m. on August 10, 2014, a large scale swimming event will take place off Edgewater Park, Cleveland, OH. The Captain of the Port Buffalo has determined that a large scale swimming event on a navigable waterway will pose a significant risk to participants and the boating public.

C. Discussion of the Final Rule

With the aforementioned hazards in mind, the Captain of the Port Buffalo has determined that this temporary safety zone is necessary to ensure the safety of participants, spectators, and vessels during the Gay Games 9 Open Water Swim event. This zone will be effective and enforced from 8 a.m. until 1 p.m. on August 10, 2014. The zone will encompass all waters of Lake Erie near the shore of Edgewater Park in Cleveland, OH within a 1000-yard radius centered around 41°29’40” N and 081°44’24” W (NAD 83).

Entry into, transiting, or anchoring within the safety zone is prohibited

unless authorized by the Captain of the Port Buffalo or his designated on-scene representative. The Captain of the Port or his designated on-scene representative may be contacted via VHF Channel 16.

D. Regulatory Analyses

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

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

We conclude that this rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zone created by this rule will be relatively small and enforced for relatively short time. Also, the safety zone is designed to minimize its impact on navigable waters. Furthermore, the safety zone has been designed to allow vessels to transit around it. Thus, restrictions on vessel movement within that particular area are expected to be minimal. Under certain conditions, moreover, vessels may still transit through the safety zone when permitted by the Captain of the Port.

2. Impact on Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered the impact of this rule on small entities. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit a portion of Lake Erie in Cleveland, Ohio between 8 a.m. and 1 p.m. on August 10, 2014.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: This safety zone will allow for the passage of vessels through the zone with the permission of the Captain of the Port. The Captain of the Port can be reached via VHF channel 16. Before the activation of the zone, we would issue local Broadcast Notice to Mariners.

3. Assistance for Small Entities

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

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

4. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

5. Federalism

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

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to

coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

7. *Unfunded Mandates Reform Act*

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

8. *Taking of Private Property*

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

9. *Civil Justice Reform*

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

10. *Protection of Children*

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

11. *Indian Tribal Governments*

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

12. *Energy Effects*

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

13. *Technical Standards*

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

14. *Environment*

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of a safety zone and, therefore it is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T09–0635 to read as follows:

§ 165.T09–0635 Safety Zone; Gay Games 9 Open Swim, Lake Erie, Cleveland, OH.

(a) *Location.* This safety zone will encompass all waters of Lake Erie near the shore of Edgewater Park in Cleveland, OH within a 1000-yard radius centered around 41°29′40″ N and 081°44′24″ W (NAD 83).

(b) *Effective and enforcement period.* This section is effective and will be enforced on August 10, 2014, from 8 a.m. until 1 p.m.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Buffalo or his designated on-scene representative.

(3) The “on-scene representative” of the Captain of the Port Buffalo is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port Buffalo to act on his behalf.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port Buffalo or his on-scene representative to obtain permission to do so. The Captain of the Port Buffalo or his on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Buffalo, or his on-scene representative.

Dated: July 25, 2014.

B.W. Roche,
Captain, U.S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. 2014–18605 Filed 8–5–14; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0225; FRL–9914–37]

Fluopicolide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends tolerances for residues of fluopicolide in or on potato, processed potato waste; and vegetable, tuberous and corm, subgroup 1C. Valent U.S.A. Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 6, 2014. Objections and requests for hearings must be received on or before October 6, 2014, 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–2014–0225, 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: Lois Rossi, 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: RDFFRNotices@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-2014-0225 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 October 6, 2014. 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-2014-0225, 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 May 23, 2014 (79 FR 29729) (FRL-9910-29), 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 3F8191) by Valent U.S.A. Corporation, 1600 Riviera Avenue, Suite 200, Walnut Creek, CA 94596. The petition requested that 40 CFR 180.627 be amended by establishing tolerances for residues of the fungicide fluopicolide, 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methylbenzamide, in or on potato, processed waste at 0.3 parts per million (ppm); and vegetable, tuberous and corm, subgroup 1C at 0.3 ppm. That document referenced a summary of the petition prepared by Valent U.S.A. Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's

response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance in or on potato, processed waste from 0.3 ppm to 1.0 ppm, and has revised the commodity terminology. The reasons for these changes are 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), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluopicolide including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluopicolide follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Fluopicolide shares a metabolite, 2,6-dichlorobenzamide (BAM), with another active ingredient, dichlobenil. Residues of BAM are considered to be of regulatory concern, and separate toxicity data and endpoints for risk assessment have been identified for

BAM. However, since increased tolerances on the commodities affected by this action do not add significantly to the BAM dietary exposure, the conclusions from the most recently conducted BAM human health risk assessment remain unchanged.

The subchronic and chronic toxicity studies for fluopicolide showed that the primary effects following exposure are in the liver. Kidney and thyroid toxicity were observed in rats only. Fluopicolide is not neurotoxic, carcinogenic, nor mutagenic. Developmental toxicity in the rabbit occurred only at doses that caused severe maternal toxicity, including death. In the rat, developmental effects were seen only at high dose levels, in the presence of maternal toxicity. Similarly, offspring effects (decreased body weight and body weight gain) in the multi-generation reproductive toxicity study occurred only at levels causing significant toxicity in parents. There is no evidence of increased quantitative susceptibility of rat or rabbit fetuses to *in utero* or postnatal exposure to fluopicolide. No toxic effects were observed in studies in which fluopicolide was administered by the dermal routes of exposure. The toxicological profile for fluopicolide suggests that increased durations of exposure do not significantly increase the severity of observed effects. Toxic effects observed in the rabbit developmental and rat chronic/cancer studies were selected as risk assessment endpoints for all durations of exposure. Fluopicolide is classified as not likely to be carcinogenic to humans and no quantification of cancer risks is required.

The toxicity profile for BAM has not changed since the last assessment EPA conducted for BAM; an analysis of the toxicology profile of BAM can be found in “2,6-Dichlorobenzamide (BAM). 2,6-Dichlorobenzamide (BAM) as a Metabolite/Degradate of Fluopicolide and Dichlobenil. Human Health Risk Assessment for Proposed Uses of Rhubarb, Dichlobenil on Caneberries (Subgroup 13–07A), and Bushberries (Subgroup 13–07B).” dated June 19, 2008, in docket ID number EPA–HQ–OPP–2007–0604.

Specific information on the studies received and the nature of the adverse effects caused by fluopicolide as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document: “Fluopicolide and its Metabolite, 2,6-Dichlorobenzamide (BAEM). Human Health Risk Assessment to Support a Petition for an Increased Tolerance on

Tuberous and Corm Subgroup 1C Vegetables,” pp. 31–35 in docket ID number EPA–HQ–OPP–2014–0225.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for fluopicolide and BAM used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of April 20, 2011 (76 FR 22045) (FRL–8859–9).

C. Exposure Assessment

The fluopicolide exposure assessment considers exposure from fluopicolide only. EPA did not reassess exposures from BAM since the proposed change in use pattern does not add significantly to the BAM dietary exposure, and residues of BAM due to fluopicolide applications are significantly lower than those from dichlobenil applications. EPA is relying on conclusions from the 2008 BAM Human Health Risk Assessment, which remain unchanged. A discussion of how BAM exposures were assessed can be found in Unit III.C. of the final rule published in the **Federal Register** of August 27, 2008 (73 FR 50563) (FRL–8377–7).

1. *Dietary exposure from food and feed uses.* In evaluating dietary

exposure to fluopicolide, EPA considered exposure under the petitioned-for tolerances as well as all existing fluopicolide tolerances in 40 CFR 180.627. EPA assessed dietary exposures from fluopicolide in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for fluopicolide; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with Food Commodity Intake Database (DEEM–FCID) Version 3.16. This software uses 2003–2008 food consumption data from the U.S. Department of Agriculture’s (USDA’s) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed 100 percent crop treated (PCT) and tolerance-level residues. iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fluopicolide does not pose a cancer risk to humans. Therefore, a quantitative dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for fluopicolide. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fluopicolide in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluopicolide. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the surface water concentrations estimated using the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS); and Screening Concentrations in Ground Water (SCI–GROW) models, the estimated environmental concentrations (EECs) of fluopicolide for chronic exposure (non-cancer) assessments are estimated to be 24.14

ppb for surface water and 0.5 ppb for ground water. Acute and cancer dietary risks were not quantified, as previously discussed.

3. *From non-dietary exposure.* i. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

ii. Fluopicolide is currently registered for the use on residential turf grass, recreational sites, and ornamental plants that could result in short-term residential exposures. EPA assessed residential exposure using the following assumptions:

a. Residential handler short-term dermal and inhalation exposures to fluopicolide when mixing, loading, and applying the formulations.

b. Residential post-application exposures via the dermal route for adults and children entering treated lawns or treated gardens and during mowing and golfing activities, and

c. Incidental non-dietary ingestion (i.e., hand-to-mouth, object-to-mouth, and soil ingestion) by children during post-application activities on treated turf.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to fluopicolide and any other substances. Although fluopicolide shares a common metabolite, BAM, with dichlobenil, quantification of risks for residues of BAM resulting from fluopicolide was not done as part of this assessment because they contribute an insignificant amount to the total BAM exposure. Furthermore, aggregate risks to BAM are not of concern. For the purposes of this tolerance action, EPA has not assumed that fluopicolide has a common mechanism of toxicity with other substances.

For information regarding EPA’s efforts to determine which chemicals

have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA’s Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA’s Web site at: <http://www.epa.gov/pesticides/cumulative/>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of quantitative susceptibility following *in utero* and/or postnatal fluopicolide exposure in the rabbit and rat developmental toxicity studies or in the 2-generation rat reproduction study. Qualitative susceptibility was observed in the rat developmental toxicity study. In this study, fetal effects (reduced growth and skeletal defects) and late-term abortions were observed at doses at which only decreased body weight gain were observed in maternal animals. There is low concern for this qualitative susceptibility because the fetal effects and late-term abortions have been well characterized and only occurred at a dose level near the limit dose. Protection for the maternal effects also protects for any effects that may occur during development. There are no residual uncertainties concerning prenatal and postnatal toxicity for fluopicolide.

3. *Conclusion regarding fluopicolide.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for fluopicolide is complete.

ii. There is no indication that fluopicolide is a neurotoxic chemical and there is no need for a

developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that fluopicolide results in increased susceptibility in *in utero* rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. Although there was some evidence of qualitative susceptibility in the rat developmental toxicity study, as discussed in Unit III.D.2., the degree of concern for the prenatal and/or postnatal toxicity is low; thus, there is no need for the 10X FQPA safety factor to account for potential prenatal or postnatal toxicity.

iv. There are no residual uncertainties identified in the exposure databases. The chronic dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluopicolide in drinking water. Although EPA has required additional data on transferable residues from treated turf for fluopicolide, EPA is confident that it has not underestimated turf exposure due to the conservativeness of the default turf transfer value and conservative assumptions in the short-term turf assessment procedures (e.g., assuming residues do not degrade over the thirty-day assessment period and assuming high-end activities on turf for every day of the assessment period). Therefore, EPA is confident that it has not underestimated postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by fluopicolide.

4. *Conclusion regarding BAM.* For reasons explained in the Unit III.D.3.ii. of the preamble to the final rule published in the **Federal Register** of August 27, 2008, EPA reduced the FQPA safety factor for BAM to 1X for inhalation and dermal exposure scenarios and retained the 10X FQPA safety factor for all other BAM exposure scenarios. EPA is relying on the findings in the preamble of the August 27, 2008 final rule and the 2008 BAM Risk Assessment for the BAM FQPA safety factor determinations for this action.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime

probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, fluopicolide is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluopicolide from food and water will utilize 13% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fluopicolide is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fluopicolide is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate average exposure through food and water with short-term residential exposures to fluopicolide.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 110 for adults and 180 for children aged 6 to less than 11 years old. Because EPA's level of concern for fluopicolide is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, fluopicolide is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus average dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is

at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for fluopicolide.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, fluopicolide is not expected to pose a cancer risk to humans.

6. *BAM.* As noted in Unit III.C., EPA does not expect the increased tolerances in this action to increase BAM exposure above what was assessed in the June 19, 2008 BAM risk assessment. None of the results of this BAM risk assessment indicated a risk from aggregate BAM exposures, including for acute and chronic risks. Similarly, since short- and intermediate-term aggregate MOEs for BAM are greater than the LOC, they represent risk estimates that are below the Agency's level of concern. Finally, EPA has determined that BAM does not pose an aggregate cancer risk for the U.S. population. EPA has relied upon the conclusions from the June 19, 2008 BAM Risk Assessment in order to make these determinations.

7. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to fluopicolide residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, liquid chromatography/tandem mass spectrometry (LC/MS/MS), is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health

Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established an MRL for fluopicolide on the subject commodities.

C. Response to Comments

EPA received one comment to the Notice of Filing that made a request to reconsider “loosening tolerances” for several pesticide petitions, including for fluopicolide. The commenter additionally noted that, “It is an issue of environmental justice that our youngest citizens—our children—are disproportionately exposed to health risks.” The commenter points to an American Academy of Pediatrics Policy statement regarding pesticide exposure in children, a Centers for Disease Control and Prevention report on human exposure to environmental chemicals, and a President's Cancer Panel regarding reducing environmental cancer risks in supporting the request to reconsider the tolerance amendments proposed for fluopicolide.

The Agency understands the commenter's concerns and recognizes that some individuals believe that certain pesticide chemicals should not be permitted in our food, or that pesticide tolerances should be “significantly tightened” as the commenter notes. However, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when EPA determines that aggregate exposure to that pesticide is safe, i.e., that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. When making this determination, EPA considers the toxicity, including any potential carcinogenicity, of the pesticide and all anticipated dietary exposures and all other exposures for which there is reliable information. EPA also gives special consideration to the potential susceptibility and exposures of infants and children to the pesticide chemical residue when making this determination. For fluopicolide, the Agency has considered all the available data, including all available data concerning the potential for carcinogenicity of fluopicolide and its metabolites, and concluded after conducting a risk assessment, that there is a reasonable certainty that no harm

will result from aggregate human exposure to fluopicolide and that, accordingly, the amended fluopicolide tolerances on potato, processed potato waste and vegetable, tuberous and corm, subgroup 1C, are safe.

D. Revisions to Petitioned-For Tolerances

Based on the data supporting the petition, EPA has determined that the proposed tolerance in or on potato, processed waste at 0.3 ppm should be established at 1.0 ppm. That determination was based on the following: Processing data previously provided for the use of fluopicolide on potato indicate that residues of fluopicolide concentrate in wet peels. Residues of fluopicolide found in or on potatoes are estimated to be in the range of 0.2 ppm to 0.25 ppm following directed soil application. Using the highest estimated value of residues found in or on potato and the theoretical concentration factor of 4.0X for potato processed waste (in accordance with EPA's Residue Chemistry Test Guidelines), EPA has determined that a tolerance of 1.0 ppm is appropriate for residues on potato, processed waste. Additionally, EPA has revised the commodity terminology to potato, processed potato waste in order to reflect the preferred designation.

V. Conclusion

Therefore, tolerances are established for residues of fluopicolide, 2,6-dichloro-N-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl]benzamide, in or on potato, processed potato waste at 1.0 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.3 ppm.

VI. Statutory and Executive Order Reviews

This final rule 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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: July 29, 2014.

Lois Rossi,

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 § 180.627, revise the following entries in the table in paragraph (a) to read as follows:

§ 180.627 Fluopicolide; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	*
Potato, processed potato waste	1.0
* * *	*
Vegetable, tuberous and corm, subgroup 1C	0.3

[FR Doc. 2014-18458 Filed 8-5-14; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0904; FRL-9912-92]

Bifenazate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of bifenazate in or on multiple commodities which are identified and discussed later in this document including tolerances with regional restrictions for timothy hay and timothy forage. In addition, this regulation removes existing tolerances on "fruit, pome, group 11" "vegetable, fruiting, group 8" and existing time-limited tolerances for "timothy, forage" and "timothy, hay" that are superseded

by this action. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 6, 2014. Objections and requests for hearings must be received on or before October 6, 2014, 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-2010-0904, 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: Lois Rossi, 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: RDfRNNotices@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-2010-0904 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 October 6, 2014. 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-2010-0904, 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 Wednesday, July 6, 2011 (76 FR 39358) (FRL-8875-6), 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 (PP1E7847) by the Interregional Research Project Number 4 (IR-4), IR-4 Project Headquarters, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.572 be amended by establishing tolerances for residues of bifenazate: Hydrazine carboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl)-methylethyl ester in or on fruit, pome, group 11-10 at 0.75 parts per million (ppm); herb, subgroup 19A dried leaves, except chervil, dried and chive, dried, at 140 ppm; herb, subgroup 19A, fresh leaves at 30 ppm; timothy, forage at 140 ppm; timothy, hay at 120 ppm; and vegetable, fruiting, group 8-10 at 2.0 ppm. That document referenced a summary of the petition prepared by Chemtura Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance level and corrected the commodity definition for certain commodities, and revised the tolerance expression for bifenazate. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on

aggregate exposure for bifenazate including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with bifenazate follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Bifenazate has low acute toxicity for the oral, dermal and inhalation routes of exposure. For subchronic oral exposures, the dog is the most sensitive species. For chronic oral exposures, the dog and the rat are equally sensitive.

Subchronic and chronic studies in rats and dogs indicate that the liver and hematopoietic system (spleen and bone marrow with associated hematological findings) are the primary target organs in these species. Additional toxicity was seen in the kidney (dogs following chronic exposure) and adrenal cortex (male rats following subchronic exposure). Decreases in body weight, body-weight gain, and food consumption were also associated with liver and hematopoietic system toxicity in several studies.

In the rat developmental toxicity study, the maternal effects consisted of clinical signs of toxicity, decreased body weight and body-weight gains, and reduced food consumption at the mid-dose. Increases in early fetal resorptions occurred at the same doses that caused maternal toxicity. In the rabbit developmental toxicity study, there were no maternal or developmental effects up to the highest dose tested (HDT). In the 2-generation rat reproduction study, the parental effects occurred at the mid-dose and consisted of decreased body weight and body-

weight gains. There were no reproductive or offspring effects up to the HDT.

In the acute neurotoxicity study, treatment related effects were seen only at the HDT, and consisted of decreased motor activity (rearing in females; center time in both sexes). In the subchronic neurotoxicity study, effects were also only seen at the HDT (34.5 milligrams/kilogram/day (mg/kg/day) and consisted of decreased landing foot splay (males), decreased fore- and hindlimb grip strength (males), decreased motor activity measurements consisting of center times (females) and rearing activity (both sexes). The level of concern (LOC) for neurotoxicity in the bifenazate database is low however because:

- The observed effects are well characterized;
- They occur only at the highest doses tested; and
- They are protected for by the studies used in the endpoint selection.

There were no observed toxicological effects in the immunotoxicity study up to the HDT.

In the mouse carcinogenicity study, males and females were tested up to 225 ppm and 175 ppm, respectively, which elicited decreased body weight and body-weight gains in females. In male mice, there was an increase in the incidence of liver adenomas only, which was not considered statistically significant by pair-wise comparison. There also was no progression of the adenomas to carcinomas in males in this study. A full battery of mutagenicity studies were negative for mutagenic or clastogenic activity. Bifenazate is classified as "not likely" to be carcinogenic to humans.

Specific information on the studies received and the nature of the adverse effects caused by bifenazate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at [http://](http://www.regulations.gov)

www.regulations.gov in document, "Bifenazate. Human-Health Risk Assessment. Section 3 Registration Request to Add New Uses on Timothy Forage and Hay; Herb, Subgroup 19A; and to Expand Existing Uses on Pome Fruit, Group 11, and Fruiting Vegetables, Group 8", dated May 15, 2014, page 40 in docket ID number EPA-HQ-OPP-2010-0904.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for bifenazate used for human risk assessment is shown in the Table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR BIFENAZATE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–49 years of age) ...	NOAEL = 10 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 0.1 mg/kg/day aPAD = 0.1 mg/kg/day	Prenatal Developmental Toxicity—Rats Developmental. LOAEL = 100 mg/kg/day based on clinical signs, decreased body weight and food consumption during the dosing period.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR BIFENAZATE FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children).	NOAEL = 600 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 6 mg/kg/day aPAD = 6 mg/kg/day	Acute Neurotoxicity Screening Battery—Rats. LOAEL = 2,000 mg/kg/day based on decreased motor activity (rearing in females).
Chronic dietary (All populations)	NOAEL = 1.0 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.01 mg/kg/day cPAD = 0.01 mg/kg/day	Chronic toxicity—Dogs. LOAEL = 8.9/10.4 mg/kg/day (M/F) based on changes in hematological and clinical chemistry parameters, and histopathology in bone marrow, liver, and kidney in the one-year dog feeding study.
Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months).	Co-critical Study NOAEL = 1.5 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x NOAEL = 0.9 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE = 100.	Carcinogenicity Study—Mouse. LOAEL = 15.4 (M) mg/kg/day based on hematology parameters and possibly kidney weights. 90-Day Subchronic—Dogs. LOAEL = 10.4 mg/kg/day based on based upon changes in hematological parameters in both sexes, increased bilirubin in the urine in males, increased absolute and relative liver weight in females and liver histopathological effects in both sexes.
Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months).	Dermal study. LOAEL = 80 mg/kg/day. UF _A = 10x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE = 100.	21-Day Dermal toxicity—Rat. LOAEL = 400 mg/kg/day based on decreased body weight in females, decreased food consumption in both sexes, increased urinary ketones, increased urinary protein, increased urinary specific gravity, and decreased urinary volume in both sexes, and increased incidence of extra medullary hematopoiesis in the spleen in both sexes.
Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months).	Rat NOAEL = 0.03 mg/L HEC = 0.0009 mg/L HED = 0.14mg/kg bw/day UF _A = 3x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE = 30.	28-Day Inhalation Toxicity—Rat LOAEL = 0.075 mg/L (M/F) on dried red material around the nose in females, lower body weights and body-weight gains, decreased food consumption, decreased heart and thymus weights in females, increased incidences of mild brown pigmentation of the spleen, and minimal to mild degeneration of the olfactory epithelium within nasal levels III, IV, and V.
Cancer (Oral, dermal, inhalation)	Bifenazate is classified as “not likely to be a human carcinogen”.		

Point of departure (POD) = a data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. Reference Dose = RfD. Male/Female = (M/F). FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). Human Equivalent Concentration (HEC) where HEC Calculations for Short- and Intermediate-term Residential Exposure: Assume residents will be exposed for 24 hrs/day and 7 days/week: HEC = NOAEL_{study} * (daily duration of exposure_{animal}/daily duration of exposure_{human}) * (days/week of exposure_{animal}/days/week of exposure_{human}) * RDDR.

- HEC = 0.03 mg/L * (6/24) * (5/7) * 0.175 = 0.00094 mg/L.

Human Equivalent Dose (HED). HED's route-to-route extrapolation converts human and animal values from mg/L concentrations to mg/kg oral equivalent doses. The equation uses a single conversion factor to account for default body weights and respiratory volumes. An activity factor is used to account for increased exposure resulting from increased respiration. Using the HEC calculated (based upon terminal airway inflammation in males), a conversion of the inhalation concentration to a dose (mg/L to mg/kg/day) was conducted as follows:

- Human-Equivalent Dose (HED, mg/kg/day) = Dose (systemic HEC value, mg/L) $\times$ A $\times$ CF (L/hr/kg) $\times$ D (hours) $\times$ AF = mg/kg

Where: A = absorption: Ratio of deposition and absorption in respiratory tract compared to absorption by the oral route. CF = conversion Factor; a L/hr/kg factor which accounts for respiratory volume and body weight for a given species and strain. D = duration; duration of daily animal or human exposure (hours). AF = activity Factor; animal default is 1. The residential human equivalent dose for bifenthrin is calculated as follows:

- Residential HED: (0.0009 mg/L) $\times$ 1 $\times$ 6 $\times$ 8 $\times$ 1 = 0.135 mg/kg/day.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to bifenthrin, EPA considered exposure under the petitioned-for tolerances as well as all existing bifenthrin tolerances in 40 CFR 180.572. EPA assessed dietary exposures from bifenthrin in food as follows:

i. *Acute exposure.* In conducting the acute dietary exposure assessment EPA used the Dietary Exposure Evaluation Model—Food Consumption Intake Database (DEEM-FCID, ver. 3.16), which incorporates consumption information from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008.

As to residue levels in food, the acute analysis for the general population, including infants and children, was unrefined and used tolerance-level residues and 100 PCT. The acute analysis for females 13 to 49 years old was highly refined and incorporated data from the USDA's Pesticide Data Program (PDP), crop field trial data, and PCT estimates. DEEM (ver. 7.81) default processing factors were assumed for all commodities excluding apple juice, grape juice, and wine/sherry. The processing factors for these commodities were reduced to 1.0, based on data from processing studies.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM-FCID, ver. 3–16 which incorporates consumption information from the USDA NHANES/WWEIA; 2003–2008. As to residue levels in food, the chronic dietary exposure analysis for all population subgroups was partially refined and used tolerance-level residues and PCT estimates. DEEM default processing factors were assumed for all commodities excluding apple juice, grape juice, and wine/sherry. The processing factors for these commodities were reduced to 1.0 based on data from processing studies.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has classified bifenthrin as “not likely” to

be a human carcinogen. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk was not conducted.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

Maximum PCT estimates were used in the acute dietary risk assessment:

Almonds: 10%; apples: 5%; apricots: 10%; beans, green: 2.5%; caneberrries: 30%; cantaloupes: 2.5%; cherries: 5%; cucumbers: 5%; grapefruit: 5%; grapes: 20%; nectarines: 10%; oranges: 2.5%; peaches: 20%; pears: 30%; pecans:

2.5%; peppers: 10%; pistachios: 2.5%; plums/prunes: 20%; potatoes: 5%; pumpkins: 5%; squash: 2.5%; strawberries: 65%; tomatoes: 10%; walnuts: 5%; and watermelon: 2.5%.

The following average PCT estimates were used in the chronic dietary risk assessment: Almonds: 5%; apples: 5%; apricots: 5%; beans, green: 1%; caneberrries: 25%; cantaloupes: 1%; cherries: 2.5%; cucumbers: 2.5%; grapefruit: 5%; grapes: 10%; nectarines: 5%; oranges: 1%; peaches: 10%; pears: 15%; pecans: 1%; peppers: 5%; pistachios: 2.5%; plums/prunes: 5%; potatoes: 5%; pumpkins: 2.5%; squash: 1%; strawberries: 45%; tomatoes: 5%; walnuts: 2.5%; and watermelon: 1%.

In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including

several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which bifentazate may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for bifentazate in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of bifentazate. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST) model and the dry bean application scenario (highest registered/proposed use rate) and the Screening Concentrations in Ground Water (SCI-GROW) model, the estimated drinking water concentrations (EDWCs) of bifentazate acute exposures are estimated to be 37.3 ppb for surface water and 0.014 ppb for ground water.

For chronic exposures for non-cancer assessments are estimated to be 11.2 ppb for surface water and 0.014 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For acute dietary risk assessment, the water concentration value of 37.3 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 11.2 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Bifentazate is currently registered for the following uses that could result in residential exposures: Ornamental plants, including bedding plants, flowering plants, foliage plants, bulb crops perennials, trees, and shrubs. EPA assessed residential exposure using the following assumptions: There is a

potential for short-term dermal and inhalation exposures by homeowners applying bifentazate. Intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners.

The residential handler exposure assessment estimates dermal and inhalation exposures for individuals using bifentazate on residential ornamentals. The quantitative exposure/risk assessment developed for residential handlers is based on the following scenarios:

- i. Mixing/loading/applying liquids with manually-pressurized handwand,
- ii. Mixing/loading/applying liquids with hose-end sprayer,
- iii. Mixing/loading/applying liquids with backpack, and
- iv. Mixing/loading/applying liquids with sprinkler can.

Unit exposure values and estimates for area treated were taken from the 2012 Residential SOPs: Gardens and Trees. An aggregate risk index (ARI) was used since the LOCs for dermal exposure (100) and inhalation exposure (30) are different. The target ARI is 1; therefore, ARIs of less than 1 result in risk estimates of concern. The ARI was calculated as follows.

$$\bullet \text{ Aggregate Risk Index (ARI)} = 1 \div [(Dermal \text{ LOC} \div Dermal \text{ MOE}) + (Inhalation \text{ LOC} \div Inhalation \text{ MOE})]$$

Short-term risk estimates for residential handlers are greatest for exposure scenarios "hose-end sprayer" and "backpack" resulting in ARIs of 80 and 66, respectively. Short-term dermal and inhalation risk estimates to residential handlers do not exceed EPA's LOC for all scenarios. All the ARIs are above 1 and do not exceed the Agency's LOC for all scenarios.

Short-term dermal exposure and risk from residential post-application have been assessed for bifentazate under the following scenarios, routes of exposure and lifestages:

- Gardens and Trees: adults (dermal) and children 6 to less than or equal 11 years old (dermal).

These lifestages are not the only lifestages that could be potentially exposed for these post-application scenarios; however, the assessment of these lifestages is health protective for the exposures and risks for any other potentially exposed lifestages. All adult and children dermal post-application risk estimates for exposure to treated trees and gardens are not of concern (MOEs ≥ 100). Details of assumptions and factors the Agency applied in residential and residential post-application exposure assessments are detailed in the 2012 Residential SOPs at

<http://www.epa.gov/pesticides/science/residential-exposure-sop.html>.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found bifentazate to share a common mechanism of toxicity with any other substances, and bifentazate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that bifentazate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicology database for bifentazate includes rat and rabbit developmental toxicity studies and a 2-generation reproduction toxicity study in rats. In the rat developmental toxicity study, the maternal effects consisted of clinical signs of toxicity, decreased body weight and body-weight gains, and reduced food consumption at the mid-dose. Increases in early fetal resorptions occurred at the same doses that caused maternal toxicity. In the

rabbit developmental toxicity study, there were no maternal or developmental effects up to the HDT. In the 2-generation rat reproduction study, the parental effects occurred at the mid-dose and consisted of decreased body weight and body-weight gains. There were no reproductive or offspring effects up to the HDT.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for bifentazate is complete.

ii. There is evidence of neurotoxicity in the bifentazate database. The level of concern for neurotoxic effects in children is low however because

- The observed effects are well characterized;
- They occur only at the highest doses tested; and
- They are protected for by the studies used in the endpoint selection.

iii. There is no evidence that bifentazate results in increased susceptibility in *in utero* rats or rabbits in the pre- or postnatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The exposure databases are sufficient to determine the nature and magnitude of the residue in food and water. For acute exposure for the general population and chronic exposure, the dietary exposure analyses are unlikely to underestimate exposure as they incorporated tolerance-level residues, 100 PCT for acute exposure, PCT for chronic exposure, and modeled drinking water estimates. For acute analysis for females 13 to 49 years, the dietary analysis is unlikely to underestimate exposure as PDP, crop field trial data, PCT estimates and modeled drinking water estimates were utilized.

EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to bifentazate in drinking water. The dietary food and drinking water exposure assessments will not underestimate the potential exposures for infants and children. The residential use (ornamentals) is not expected to result in post-application exposure to infants and children as well as incidental oral exposure of toddlers. The post-application exposure assessments are based upon the residential SOPs, which are based upon reasonable worst-case assumptions and are not expected to underestimate risk. These assessments will not

underestimate the exposure and risks posed by bifentazate.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to bifentazate will occupy <1.9% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure. The acute dietary exposure estimates are not of concern to EPA (<100% aPAD) for the general U.S. population and all population subgroups

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to bifentazate from food and water will utilize 74% of the cPAD for children 1 to 2 years old the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of bifentazate is not expected.

3. *Short- and intermediate-term risks.* Short- and intermediate-term aggregate exposures take into account short- and intermediate-term residential exposures plus chronic exposure to food and water (considered to be a background exposure level). Bifentazate is currently registered for uses that could result in short- and intermediate-term residential exposures.

The short- and intermediate-term toxicological PODs for bifentazate are the same for each route of exposure. Therefore, for residential exposure scenarios, only short-term exposures were assessed, and are considered to be protective of intermediate-term exposure and risk.

It was appropriate to aggregate postapplication dermal exposures with dietary (food and water) exposures. The dermal postapplication exposure to gardens and ornamentals scenario is the residential exposure scenario with the greatest risk estimate for both adults and children 6 ≤ 11 years old; therefore, the exposure estimates for this scenario are

protective of any other exposure scenarios.

For the adult and children 6 ≤ 11 years old short- and intermediate-term aggregate risk assessment, the MOE approach was used to estimate aggregate exposures as there are different PODs for oral and dermal routes of exposure but the LOC are the same. The chronic dietary exposure estimate for Adults 20–49 years old and Children 6–12 years old were used in the aggregate risk estimate for adults and children 6 ≤ 11 years old, respectively.

All of the adult and children 6 ≤ 11 years old chronic dietary + dermal aggregate risk estimates do not exceed EPA's LOC (MOEs ≥ 100).

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, bifentazate (classified as “not likely” to be a human carcinogen) is therefore not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to bifentazate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies are available to enforce the tolerance expression.

For plant commodities, high-performance liquid chromatography with oxidative coulometric electrochemical detector (HPLC/ELCD) Method UCC–D2341 is available as a primary enforcement method for the combined residues of bifentazate and its metabolite D3598. The method has been forwarded to the United States Food and Drug Administration (FDA) for inclusion in the Pesticides Analytical Manual, Volume II (PAM II). The limit of quantification (LOQ) and limit of detection (LOD) of Method UCC–D2341 are 0.01 and 0.005 ppm, respectively. In addition, a liquid chromatographic system with tandem mass spectrometers (LC–MS/MS) method (NCL ME 245) was recently submitted as a confirmatory method and has been forwarded to FDA.

For livestock commodities, HPLC methods with fluorescence detection or ELCD are available as primary methods for the enforcement of tolerances for residues of bifentazate and its regulated metabolites in livestock matrices. The methods have undergone a successful validation by the Agency and have been forwarded to FDA for inclusion in PAM

II. In addition, the LC-MS/MS Method NCL ME 259 was recently submitted as a confirmatory method, and this method was also forwarded to FDA. The validated LOQ was 0.01 ppm for each analyte. The LOD was reported as 0.005 ppm.

The methods 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.

There are currently no established Codex MRLs for bifenazate in/on herbs, and timothy forage and hay. Codex MRLs are established for pome fruits (0.7 ppm), chili peppers (3 ppm), sweet peppers (2 ppm) and tomato (0.5 ppm), but not for other members of Vegetable, fruiting, group 8-10.

The U.S. is establishing a tolerance for Vegetable, fruiting, group 8-10 at 4.0 ppm for residues of bifenazate (and its metabolite). There is an existing U.S. tolerance of 2 ppm for Vegetables, fruiting, crop, group 8. This tolerance was established in 2003 prior to the implementation of the Organization for Economic Co-Operation and Development (OECD) calculation procedures. In 2007 Codex established the MRLs for chili peppers, sweet peppers and tomato and relied on the U.S. field trial data. Codex chose not to establish a group tolerance for the fruiting vegetables but instead established separate Codex MRLs for tomato, peppers and chili peppers using the highest observed residue approach. The approach taken by Codex is not in line with how the U.S. establishes crop group tolerances. Further, using the

OECD calculation procedures and based on data from bell and non-bell pepper studies conducted in the U.S., and tomato studies conducted in Canada and the U.S. results in the recommended tolerance of 4.0 ppm.

EPA is establishing the U.S. tolerance for residue in or on pome fruit at 0.7 ppm, in harmonization with the established Codex MRL.

C. Revisions to Petitioned-For Tolerances

After reviewing supporting data and information, EPA modified certain elements of the petition as proposed in the notice of filing, as follows:

1. EPA corrected the proposed commodity definitions, "Herb, subgroup 19A, fresh leaves" and "Herb, subgroup 19A, dried leaves, except chervil, dried and chive, dried" to read "Herb subgroup 19A, except chervil and chive" to specify crop coverage and for accuracy and consistency in naming of commodities.

2. Using the OECD tolerance-calculation procedures, the Agency modified proposed tolerance levels for certain commodities as follows:

i. A proposed tolerance at 140 ppm for "Herb, subgroup 19A, dried leaves, except chervil, dried and chive, dried" was established for "Herb, subgroup 19A, except chervil and chive" at 300 ppm, and

ii. A proposed tolerance at 140 ppm on timothy, forage, was established at 200 ppm (tolerance with regional registrations), and a proposed tolerance of 120 ppm on timothy, hay, was established at 150 ppm (tolerance with regional registrations).

3. As petitioned-for, EPA is establishing tolerances with regional registrations for timothy, forage and timothy, hay for regional use in two counties, Eureka and Humboldt, in the State of Nevada. Applications of bifenazate can only be made to timothy that is intended for use as horse feed. Livestock feedstuffs are not derived from the proposed crops of the subject petition, except for timothy. The Agency is removing existing time-limited tolerances established for bifenazate under section 18 emergency exemptions for timothy, forage and timothy, hay at 50 ppm and 150 ppm, respectively, as they are superseded by this action.

4. As previously stated, the U.S. tolerance for Vegetable, fruiting, group 8-10 is being changed to 4.0 ppm. This is based the use of the OECD calculation procedures on data from bell and non-bell pepper studies conducted in the United States, and tomato studies conducted in Canada and the United States.

In addition, the Agency is revising the tolerance expressions for bifenazate tolerances in order to conform to current EPA policy as follows:

5. 40 CFR § 180.572(a)(1) is revised to read as follows: Tolerances are established for residues of bifenazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate) including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified are to be determined by measuring only the sum of bifenazate and its metabolite, diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester, (calculated as the stoichiometric equivalent of bifenazate) in or on food commodities, and

6. The tolerance expression for 40 CFR § 180.572(a)(2) is modified as follows: Tolerances are established for residues of bifenazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate) including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified are to be determined by measuring only the sum of bifenazate and its metabolites diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester; 1,1'-biphenyl, 4-ol; and 1,1'-biphenyl, 4-oxysulfonic acid (calculated as the stoichiometric equivalent of bifenazate) in or on food commodities.

V. Conclusion

Therefore, tolerances are established for residues of bifenazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate) including its metabolites and degradates, in or on Herb subgroup 19A, except chervil and chive at 300 ppm, Timothy, forage at 200 ppm, Timothy, hay at 150 ppm, Fruit, pome, group 11-10 at 0.7 ppm and Vegetable, fruiting, group 8-10 at 4.0 ppm. In addition, this regulation removes existing tolerances on "fruit, pome, group 11" "vegetable, fruiting, group 8" and existing time-limited tolerances for "timothy, forage" and "timothy, hay" that are superseded by this action.

VI. Statutory and Executive Order Reviews

This final rule 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 final rule

has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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: July 21, 2014.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.572 is amended as follows:

■ a. Revise the introductory text in paragraph (a)(1);

■ b. Alphabetically add commodities to the table in paragraph (a)(1);

■ c. Remove from the table in paragraph (a)(1) the entries for "Fruit, pome, group 11" and "Vegetable, fruiting, group 8";

■ d. Revise the introductory text in paragraph (a)(2);

■ e. Remove and reserve paragraph (b); and

■ f. Add paragraph (c) to read as follows:

§ 180.572 Bifenazate; tolerance for residues.

(a) *General.* (1) Tolerances are established for residues of bifenazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate) including its metabolites and degradates, in or on the commodities listed in the following table.

Compliance with the tolerance levels specified are to be determined by measuring only the sum of bifenazate and its metabolite, diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester, (calculated as the

stoichiometric equivalent of bifenazate) in or on the following food commodities:

Commodity	Parts per million
* * * * *	
Fruit, pome, group 11–10	0.7
* * * * *	
Herb, subgroup 19A, except chervil and chive	300
* * * * *	
Vegetable, fruiting, group 8–10 ..	4.0
* * * * *	

(2) Tolerances are established for residues of bifenazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate) including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified are to be determined by measuring only the sum of bifenazate and its metabolites diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester; 1,1'-biphenyl, 4-ol; and 1,1'-biphenyl, 4-oxysulfonic acid (calculated as the stoichiometric equivalent of bifenazate) in or on the following food commodities:

* * * * *

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(l), are established for residues of bifenazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate) including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified are to be determined by measuring only the sum of bifenazate and its metabolite, diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester, (calculated as the stoichiometric equivalent of bifenazate) in or on the following food commodities:

Commodity	Parts per million
Timothy, forage	200
Timothy, hay	150

* * * * *

[FR Doc. 2014–18041 Filed 8–5–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 228

[EPA–R06–OW–2014–0234; FRL–9914–59–Region 6]

Ocean Dumping: Cancellation and Modification of Final Site Designations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) today cancels the final designation of two Ocean Dredged Material Disposal Sites (ODMDSs) located in the Gulf of Mexico near the Houma Navigational Canal (HNC) and near the Mississippi River Gulf Outlet (MRGO) Canal, Louisiana. Both sites are EPA-approved ocean dumping sites for the disposal of suitable dredged material. This final action is being taken because there is no clear future need for the sites. Additionally, EPA is modifying the period of use, use restriction, and name of the Homeport Project ODMDS located in the Gulf of Mexico offshore of Port Aransas, Texas.

DATES: This Final Rule is effective on September 5, 2014.

ADDRESSES: The EPA established a docket for this action under Docket No.

EPA–R06–OW–2014–0234. All documents in the docket are listed on the <http://www.regulations.gov> Web site. Publicly available docket materials are available electronically through <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Jessica Franks, Ph.D., Marine and Coastal Section (6WQ–EC), Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733, telephone (214) 665–8335, fax number (214) 665–6689; email address franks.jessica@epa.gov.

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

I. Potentially Affected Persons

Persons potentially affected by this action include those who seek or might seek permits or approval by EPA to dispose of dredged material into ocean waters pursuant to the Marine Protection Research and Sanctuaries Act, 33 U.S.C. 1401 *et seq.* The Final Rule would be relevant to persons, including organizations and government bodies seeking to dispose of dredged material in ocean waters offshore of Terrebonne, Louisiana, the Mississippi River Gulf Outlet Canal, Louisiana, and Corpus Christi, Texas. Currently, the U.S. Army Corps of Engineers (Corps) and other persons with permits to use designated sites offshore Terrebonne, Louisiana, the Mississippi River Gulf Outlet Canal, Louisiana, and Corpus Christi, Texas would be most impacted by this final action. Potentially affected categories and persons include:

Category	Examples of potentially regulated persons
Federal government	USACE Civil Works and O & M projects; other Federal agencies, including the Department of Defense.
Industry and general public	Port authorities, marinas and harbors, shipyards and marine repair facilities, berth owners.
State, local and tribal governments	Governments owning and/or responsible for ports, harbors, and/or berths, Government agencies requiring disposal of dredged material associated with public works projects.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding persons likely to be affected by this action. For any questions regarding the applicability of this action to a particular entity, please refer to the contact person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

II. Background

Section 102(c) of the Marine Protection, Research, and Sanctuaries Act (MPRSA) of 1972, as amended, 33 U.S.C. 1401 *et seq.*, gives the Administrator of EPA the authority to designate sites where ocean disposal may be permitted. On October 1, 1986, the Administrator delegated the authority to designate ocean disposal sites to the Regional Administrator of the Region in which the sites are located. These cancellations and

modification are being made pursuant to that authority.

The EPA Ocean Dumping Regulations promulgated under MPRSA (40 CFR Chapter I, Subchapter H, § 228.11) state that modifications in disposal site use which involve withdrawal of disposal sites from use or permanent changes in the total specified quantities or types of wastes permitted to be discharged to a specific disposal site will be made by promulgation in this part 228. These site cancellations and modification of types of wastes permitted to be discharged to a specific disposal site are being published as final rulemaking in accordance with § 228.11(a) of the Ocean Dumping Regulations, which permits the withdrawal of designated disposal sites from use or changes in the total specified quantities or types of wastes permitted to be discharged to a specific disposal site based upon

changed circumstances concerning use of the site.

III. Final Action

The final cancellation of the designations of these sites is needed as a housekeeping measure. In essence, these ODMDSs either are no longer a suitable disposal option or have no foreseeable need. The Houma ODMDS is now partially occupied by the Houma Navigational Canal. The U. S. Corps of Engineers has re-aligned the Cat Island Pass portion of the HNC several times since the construction of this federal navigation channel in order to retain a channel segment that requires little maintenance dredging due to the natural hydrodynamics in the vicinity. This particular portion of the HNC Cat Island Pass channel is characterized by an area of deeper water (erosional zone) that is moving westwards. Once this deeper water erosional zone has moved far

enough west from the Corps' channel alignment that area of the channel begins to shoal (becomes a depositional zone). To avoid increased maintenance dredging costs, the Corps re-aligns this portion of the channel westwards to "keep up" with the deeper water zone as it continues to migrate westwards. The Houma ODMDS is located on the west side of this channel, and the deeper water zone has migrated into the ODMDS boundaries. The Houma ODMDS has not been used for more than twenty (20) years. Instead, dredged material from the HNC has been used beneficially under section 404 of the Clean Water Act on the two (2) single point discharge (SPD) sites located within the ODMDS. It is the Corps intention to continue this practice. As such, this type of placement is excluded by definition from regulation by MPRSA. De-designation of the Houma ODMDS will allow the Corps to expand the beneficial use of dredged material for the creation of durable islands for seasonal bird nesting areas regulated under section 404 of the Clean Water Act.

The Mississippi River-Gulf Outlet (MRGO) ODMDS is no longer needed. On June 5, 2008 the Assistant Secretary of the Army for Civil Works forwarded the Final MRGO Deep-Draft De-authorization Report to Congress officially de-authorizing the MRGO from the Gulf Intercoastal Water Way (GIWW) to the Gulf of Mexico as a federal navigation project. The report also authorized the construction of a rock closure structure across MRGO which was completed in late July 2009.

The modification of the period of use and use restriction on the Homeport Project ODMDS is needed to change the use of the site to include suitable dredged material from the greater Corpus Christi, Texas vicinity over an indefinite period of time. The Homeport Project ODMDS was designated to provide a disposal area for placement of suitable construction dredge material from the U.S. Navy's Homeport Project at Corpus Christi/Ingleside, Texas. The Homeport Project never materialized and therefore, the ODMDS was never used. Use of the ODMDS was limited to suitable dredged material from the Homeport Project over a 50 year period. There is a need for placement of construction dredged material from the Corpus Christi Channel Channel Improvement Project (CIP) as described in the Final Environmental Impact Statement (FEIS) for the *Corpus Christi Ship Channel Channel Improvements Project Corpus Christi and Nueces Bays Nueces and San Patricio Counties, Texas* published in April 2003. Based

on the FEIS, suitable dredged material will be placed beneficially in the location of the Homeport Project ODMDS under section 404 of the Clean Water Act (CWA). CWA section 404 has jurisdiction in the Territorial Sea or coastal waters from the baseline to three (3) nautical miles seaward. Because the Homeport Project ODMDS is located beyond the boundary of the Territorial Sea and in the open ocean, the CWA section 404 does not have jurisdiction. As a result there is a need to change the use restriction placed on the Homeport Project ODMDS to include suitable dredged material from the greater Corpus Christi, Texas vicinity. Since dredged material placement at this ODMDS is expected to be an on-going process over many years, the period of use is being changed to continuing use. EPA is also changing the name of the Homeport Project ODMDS to Corpus Christi New Work ODMDS. The current name is no longer applicable since it was the name of the project at the time the ODMDS was designated.

IV. Responses to Comments

The proposed rule was published in the **Federal Register** on April 21, 2014, as docket number EPA-R06-OW-2014-0234. The comment period closed on June 5, 2014. The EPA received two comments on the proposed rule from two entities. These comments are responded to here.

1. Request for Geographic Coordinates

NOAA asked for the geographic coordinates for the two ODMDS being cancelled. The Houma Navigation Channel ODMDS is bounded by the following coordinates (North American Datum from 1927): 29°05'22.3" N., 90°34'43" W.; 29°02'17.8" N., 90°34'28.4" W.; 29°02'12.6" N., 90°35'27.8" W.; 29°05'30.8" N., 90°35'27.8" W.

The Mississippi River Gulf Outlet ODMDS is bounded by the following coordinates (North American Datum from 1927): 29°32'35" N., 89°12'38" W.; 29°29'21" N., 89°08'00" W.; 29°24'51" N., 88°59'23" W.; 29°24'28" N., 88°59'39" W.; 29°28'59" N., 89°08'19" W.; 29°32'15" N., 89°12'57" W.

2. Comment Regarding NHPA Section 106 Consultation

The Choctaw Nation of Oklahoma requested to be a consulting party under Section 106 of the National Historic Preservation Act for the portion of the project in Louisiana under Section 106.

The cancellation of the Houma ODMDS and Mississippi River Gulf Outlet ODMDS do not have the potential to effect historic resources

listed on or eligible for listing on the National Register. Cancellation of these sites by this Notice does not authorize any action or ground disturbance activities which would have the potential to effect resources. Therefore, Section 106 review is not necessary for this action.

V. Administrative Review

1. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993) EPA must determine whether the regulatory action is "significant," and therefore subject to office of Management and Budget (OMB) review and other requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to lead to a rule that may:

(a) Have an annual effect on the economy of \$100 million or more, or adversely affect in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or communities;

(b) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(c) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; Or

(d) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

This final rule should have minimal impact on State, local, or Tribal governments or communities. Consequently, EPA has determined that this final rule is not a "significant regulatory action" under the terms of Executive Order 12866.

2. Paperwork Reduction Act

The Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, is intended to minimize the reporting and recordkeeping burden on the regulated community, as well as to minimize the cost of Federal information collection and dissemination. In general, the Act requires that information requests and record-keeping requirements affecting ten or more non-Federal respondents be approved by OMB. Since the final rule would not establish or modify any information or recordkeeping requirements, but only clarifies existing requirements, it is not subject to the provisions of the Paperwork Reduction Act.

3. Regulatory Flexibility Act, as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

This final rule will not impose any requirements on small entities. The modification of the Homeport Project ODMDS broadens the use of the site providing an additional option for dredged material placement in the Corpus Christi, Texas vicinity. The removal of the Houma ODMDS will allow for the beneficial use of dredged material under CWA Section 404 for the creation of bird islands. The closing of the Mississippi River Gulf Outlet Navigation Channel was mandated by Congress and therefore the associated ODMDS is no longer needed.

For these reasons, the Regional Administrator certifies, pursuant to section 605(b) of the RFA, that the final rule will not have a significant economic impact on a substantial number of small entities.

4. Unfunded Mandates Reform Act

This final rule contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) of 1995 (Pub. L. 104-4) for State, local, or tribal governments or the private sector that may result in estimated costs of \$100 million or more in any year. It imposes no new enforceable duty on any State, local or tribal governments or the private sector nor does it contain any regulatory requirements that might significantly or uniquely affect small government entities. Thus, the requirements of section 203 of the UMRA do not apply to this final rule.

5. Executive Order 13132: Federalism

Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. “Policies that have federalism implications” are defined in the Executive Order to include

regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.”

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132.

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

Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure “meaningful and timely input by Tribal officials in the development of regulatory policies that have Tribal implications.” This final rule does not have Tribal implications, as defined in Executive Order 13175.

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

This Executive Order (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be “economically significant” as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, EPA must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by EPA. This final rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866, and because EPA does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

8. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use Compliance With Administrative Procedure Act

This final rule is not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355 (May 22, 2001)) because it is not a significant

regulatory action under Executive Order 12866.

9. National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (“NTTAA”), Public Law 104-113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. This final rule does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

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

Executive Order 12898 (59 FR 7629) directs Federal agencies to determine whether the Final Rule would have a disproportionate adverse impact on minority or low-income population groups within the project area. The Final Rule would not significantly affect any low-income or minority population.

List of Subjects in 40 CFR Part 228

Environmental protection, Water pollution control.

Dated: July 18, 2014.

Samuel Coleman,

Deputy Regional Administrator, Region 6.

In consideration of the foregoing, EPA amends part 228, chapter I of title 40 of the Code of Federal Regulations as follows:

PART 228—CRITERIA FOR THE MANAGEMENT OF DISPOSAL SITES FOR OCEAN DUMPING

■ 1. The authority citation for part 228 continues to read as follows:

Authority: 33 U.S.C. 1412 and 1418.

■ 2. Section 228.15 is amended by:
 ■ a. Removing and reserving paragraphs (j)(1) and (j)(4);
 ■ b. Revising paragraph (j)(16) introductory text; and
 ■ c. Revising paragraphs (j)(16)(v) and (j)(16)(vi).

The revisions read as follows:

§ 228.15 Dumping sites designated on a final basis.

* * * * *

(j) * * *

(16) Corpus Christi New Work ODMDS, Corpus Christi, Texas.

* * * * *

(v) *Period of Use:* Continuing use.

(vi) *Restrictions:* Disposal shall be limited to suitable dredged material

from the greater Corpus Christi, Texas vicinity. Disposal shall comply with conditions set forth in the most recent approved Site Management and Monitoring Plan.

* * * * *

[FR Doc. 2014-18619 Filed 8-5-14; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket Nos. 10-90, 14-58; FCC 14-98]

Connect America Fund, ETC Annual Reports and Certifications

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) finalizes decisions to use on a limited scale Connect America funding for rural broadband experiments in price cap areas that will deploy new, robust broadband to consumers. The Commission will use these rural broadband experiments to explore how to structure the Phase II competitive bidding process in price cap areas and to gather valuable information about interest in deploying next generation networks in high-cost areas.

DATES: Effective September 5, 2014, except for the application process and reporting requirements that contain new or modified information collection requirements that will not be effective until approved by the Office of Management and Budget. The Commission will publish a document in the **Federal Register** announcing OMB approval.

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SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order in WC Docket Nos. 10-90, 14-58; FCC 14-98, adopted on July 11, 2014 and released on July 14, 2014. The full text of this document, including all appendices, is available for public inspection during regular business hours in the FCC Reference Center, Room CY-A257, 445 12th Street SW., Washington, DC 20554. Or at the following Internet address: http://transition.fcc.gov/Daily_Releases/Daily_Business/2014/db0714/FCC-14-98A1.pdf. The Further Notice of

Proposed Rulemaking (FNPRM) that was adopted concurrently with the Report and Order will be published elsewhere in the **Federal Register**.

I. Introduction

1. Today the Commission takes further steps to implement the Connect America Fund to advance the deployment of voice and broadband-capable networks in rural, high-cost areas, including extremely high-cost areas, while ensuring that rural Americans benefit from the historic technology transitions that are transforming our nation's communications services. The Commission finalizes decisions to use on a limited scale Connect America funding for rural broadband experiments in price cap areas that will deploy new, robust broadband to consumers. The Report and Order (Order) establishes a budget for these experiments and an objective, clear cut methodology for selecting winning applications, building on the record from the *Tech Transitions FNPRM*, 79 FR 11366, February 28, 2014. The Commission describes the application process and announces that formal applications must be submitted by 90 days from release of the Order. The Commission will use these rural broadband experiments to explore how to structure the Phase II competitive bidding process in price cap areas and to gather valuable information about interest in deploying next generation networks in high-cost areas.

II. Discussion

2. The Commission explained in the *Tech Transitions Order*, 79 FR 11327, February 28, 2014, that it must "ensure that all Americans benefit from the technology transitions, and that it gains data on the impact of technology transitions in rural areas, including Tribal lands, where residential consumers, small businesses and anchor institutions, including schools, libraries and health care providers, may not have access to advanced broadband services." In the Order, the Commission adopts certain parameters and requirements for the rural broadband experiments that will assist us with accomplishing these goals. The Commission expects these experiments to provide critical information regarding which and what types of parties are willing to build networks that will deliver services that exceed our current performance standards for an amount of money equal to or less than the support amounts calculated by the adopted Phase II Connect America Cost Model. In addition to gathering information

relevant to broader questions implicated by technology transitions, the Commission expects these experiments also will inform key decisions that the Commission will be making in the coming months regarding the Connect America Fund. The experiments will not delay implementation of Connect America Phase II or further reforms for rate-of-return carriers. The Commission still expects to implement the offer of model-based support to price cap carriers in the coming months, and it will resolve how the Connect America Fund will address the challenges of providing service to the most remote, difficult to serve areas of the country. In addition, in the coming months, the Commission expects to be considering near-term reforms for rate-of-return carriers, based on the record it will shortly receive in response to the recent *Connect America Fund FNPRM*, 79 FR 39196, July 9, 2014, while it continues to develop a Connect America Fund for those carriers.

3. The Commission adopts a budget of \$100 million for funding experiments in price cap areas focused on bringing robust, scalable broadband networks to residential and small business locations in rural communities that are not served by an unsubsidized competitor that offers voice and Internet access delivering at least 3 Mbps downstream/768 kbps upstream. As explained in detail below, the funding will be available to serve locations in both high-cost and extremely high-cost areas, thereby advancing our implementation of both Phase II and the Remote Areas Fund. The Commission also determines the objective methodology for selecting projects among the applications it receives for the experiments. Given the manner in which the Commission has structured the budget and the selection criteria, it believes that it will be able to fund a range of diverse projects throughout the country. Finally, the Commission outlines the conditions that entities participating in the experiments must meet in order to continue to receive such support, including specific eligibility, build-out and accountability requirements, and establish the measures to ensure compliance with these conditions.

4. In the *Technology Transitions Order*, the Commission noted our desire to work cooperatively with other governmental entities to advance our shared objectives of ensuring access to broadband services. The Commission noted that it was "particularly interested in how States, localities, Tribal governments, and other non-federal governmental bodies can provide assistance, through matching

funds, in-kind contributions or other regulatory approvals and permits, to improve the business case for deployment of next generation networks.” The Commission will be monitoring the progress of the selected projects and hope that they may serve as case studies for best practices in how coordinated governmental action can improve the business case for the delivery of broadband services in rural, high-cost areas. The Commission also seeks comment in the concurrently adopted FNPRM regarding measures the Commission could take in the Phase II competitive bidding process to create incentives for state and other governmental entities to contribute funding to support the extension of broadband-capable networks.

A. Budget

5. In the *Tech Transitions FNPRM*, the Commission sought comment on the amount of support it should make available for the rural broadband experiments. Here, the Commission adopts a budget of \$100 million for funding experiments. The Commission previously authorized two rounds of \$300 million Connect America Phase I funding to quickly bring broadband to unserved communities in price cap territories. The Commission now concludes it is appropriate to provide another round of funding in price cap territories that will advance our swift implementation of Phase II.

6. The Commission concludes that adopting a budget of \$100 million for these rural broadband experiments will best balance our priorities and policy goals. Specifically, this budget should solicit meaningful interest among a range of entities that will enable us to examine, on a limited scale, key policy questions the Commission identified in the *Tech Transitions Order*. The Commission intends to test on a limited scale the use of a competitive bidding process to award support to provide robust broadband to serve fixed locations using both wireline and wireless technologies. Although many parties claim that the Commission should maximize the number of experiments that get funding and advocate adoption of a budget that exceeds the \$100 million the Commission adopts today, it notes that the Commission’s goal is not to fund as many experiments as possible, but rather to advance implementation of the Connect America Fund. The Commission is mindful of our commitment not to delay the implementation of Phase II. It could be administratively burdensome to oversee the necessary steps to authorize a large

number of experiments, which likely would divert Commission resources from resolving broader policy issues regarding implementation of the Connect America Fund in both price cap and rate-of-return areas. Instead, the Commission’s goal is to quickly gather data from submitted formal proposals about various technologies in different geographic areas to inform our judgment as it addresses important policy issues regarding how to maintain universal access in rural areas during technology transitions. The Commission expects that what it learns from the formal applications and selection process will inform our decisions in the coming months as to how to implement a Phase II competitive bidding mechanism that will maximize the participation of a variety of entities and use targeted funding to expand efficiently the availability of voice and broadband-capable infrastructure.

7. *Source of Funds*. As the Commission proposed in the *Tech Transitions FNPRM*, the funding for the rural broadband experiments will be drawn from the Connect America reserve account, which is projected to have approximately \$220 million in funding as of the third quarter of 2014 that has not already been allocated to a specific program. The Commission finds that using the reserve account to fund the experiments will help achieve the goals the Commission set for the Connect America Fund. Not only are the experiments themselves designed to encourage the deployment of robust networks capable of offering voice and broadband services to consumers in high-cost areas, the experiments will also help the Commission design the Phase II competitive bidding process and the Remote Areas Fund to efficiently achieve this goal throughout the country. Using unallocated support from the reserve account will also ensure that the Commission will not increase the size of the Universal Service Fund or Connect America budget, that it will not increase the contribution burden on consumers, and that it will not divert resources from other universal service programs. The Commission will consider appropriate treatment of any unallocated funds in the future.

B. Support Term

8. The Commission concludes that it will focus the experiments on projects seeking 10 years of recurring support, rather than proposals for projects seeking one-time support. In the *Tech Transitions Order*, the Commission set a general framework for rural broadband experiments. The Commission adopted

a support term of “up to ten years” and indicated that it would accept proposals for one-time or recurring support. Subsequently, in April, the Commission adopted a support term of 10 years for the competitive bidding process in the *Connect America Fund Order*, 79 FR 39164, July 9, 2014. One of the Commission’s primary objectives for these experiments is to learn how to structure a competitive bidding process for recurring support. The Commission therefore concludes that soliciting proposals for projects with the same 10-year term as will be available to bidders in Phase II will best inform us regarding the level of interest among potential providers in the Phase II competitive bidding process. Moreover, permitting entities to define the length of their support terms would add to the complexity of administering the experiments.

C. Eligibility

1. Eligible Areas

9. In the *USF/ICC Transformation FNPRM*, 76 FR 78384, December 16, 2011, the Commission proposed that census blocks should be the minimum geographic areas for which support will be provided through the Phase II competitive bidding process, and sought comment on whether using census tracts, bidder-defined groups, or another approach would best meet the needs of bidders in the competitive bidding process. A number of commenters expressed a preference for using the same census blocks that are subject to the offer of model-based support for the Phase II competitive bidding process. In the *Tech Transitions Order*, the Commission concluded that proposals for rural broadband experiments in price cap territories would be entertained at the census tract level, with funding provided only for locations in eligible census blocks as determined by the Connect America Cost Model. The Commission did so because it was concerned that making larger geographic areas, such as counties, the minimum geographic area for an experimental proposal potentially could deter participation in this experiment from smaller providers. Census blocks where the model calculated an average cost that exceeded the likely extremely high-cost threshold were not excluded from eligibility, allowing applicants to submit proposals to serve locations in these areas if they determined it was economically feasible to do so with the assurance of support.

10. The rural broadband experiments, in addition to providing robust last-mile broadband service to consumers in rural

communities, will be used to test a potential competitive bidding process for Phase II, providing us the opportunity to make any adjustments that may be necessary before full-scale implementation in Phase II. Based on our review of the expressions of interest, the Commission now concludes that these objectives will best be realized by accepting rural broadband experiment proposals in price cap areas at both the census tract level and the census block level. The Commission recognizes that some parties may be able to submit cost-effective proposals that would encompass all of the eligible census blocks within a tract, and it continues to encourage these parties to file such proposals. For entities whose current operations do not allow them to design projects on this scale that make business sense, the Commission waives the requirement to file proposals at the census tract level. By accepting proposals at the census block level, the Commission hopes to provide greater flexibility to parties and encourage a greater number of entities to participate in the rural broadband experiments. For example, smaller entities may not be able to serve areas as large as census tracts, but would be interested in submitting proposals for smaller neighborhoods that they may already be well positioned to serve. Permitting applicants to aggregate census blocks themselves, rather than having to work within the pre-defined framework of census tracts, will encourage greater participation among these entities. Moreover, this approach provides an opportunity for entities to engage in an incremental expansion into neighboring areas, allowing parties to leverage economies of scale to provide broadband in an efficient manner that benefits consumers. Finally, allowing rural broadband experiment proposals on the census block level will help us determine whether the census block approach that the Commission proposed to use for the Phase II competitive bidding process is administratively feasible and straightforward for both Commission staff and applicants.

11. Proposals must be for census blocks eligible for funding in the rural broadband experiments with a cost per location exceeding the Connect America Phase II funding threshold (\$52.50), but below the extremely high-cost threshold (\$207.81), and not served by an unsubsidized competitor offering voice service and Internet access providing 3 Mbps downstream/768 kbps upstream as identified by the National Broadband Map. The Commission requires applicants to commit to serving the total

number of price cap locations in a given census block. For instance, if a census block has 100 total locations, with 50 of those locations eligible for funding, an entity must commit to serve 100 locations, with the understanding that the support amount determined by the cost model covers only those 50 eligible locations. Entities also may choose to include additional locations in adjacent census blocks where the average cost per location exceeds the extremely high-cost threshold if they determine that it is economically feasible to do so with the support they are requesting for the eligible census block.

12. In the *Tech Transitions FNPRM*, the Commission sought comment on whether to allow applicants to propose to serve partially-served census blocks, which are not eligible for the offer of model-based support to price cap carriers because they are also served by an unsubsidized competitor. After reviewing the record, the Commission concludes that the complexity of implementing such an approach would likely delay implementation of the experiments. As NCTA notes, allowing entities to bid on partially-served census blocks would likely substantially increase the challenges of administering the experiments, given the lack of a reliable source of data on broadband availability below the census block level. Further, CenturyLink observes that allowing partially-served blocks would require the Commission to adjust model-based support amounts and conduct a challenge process. Because doing so would add complexity and time, as well as divert Commission attention and resources, the Commission declines to allow applicants to propose to serve partially-served census blocks. Our focus for the experiments at this point is to advance the deployment of next generation networks to areas unserved by an unsubsidized competitor as quickly and efficiently as possible and to understand how the Phase II competitive bidding process should be best fashioned. Allowing applicants to bid on partially-served census blocks would pose a number of administrative burdens on Commission staff, and the potential obstacles to conducting sub-census block challenges for these experiments outweigh the marginal benefits.

13. The Commission also decides that it will accept rural broadband experiment proposals only from entities that seek to provide service in price cap territories. Over the coming months, the Commission will be focused on reviewing the record it will shortly receive regarding near term and longer term reforms to develop a Connect

America Fund for rate-of-return carriers. The Commission believes it is prudent to focus our efforts on these issues, rather than confronting the many difficult issues associated with the potential implementation of rural broadband experiments in rate-of-return areas.

14. The Commission sought comment in the *Tech Transitions FNPRM* on whether to adjust the offer of support for a Phase II state-level commitment if rural broadband experiment funding is awarded prior to the offer of model-based support to price cap carriers. A number of commenters supported this proposal. The Commission adopts this approach, concluding that it furthers our policy of not providing duplicative support in a given area. Specifically, once winning bidders are identified, the Wireline Competition Bureau (the Bureau) will remove the relevant census blocks from the list of eligible census blocks and make additional census blocks available by raising the extremely high-cost threshold so as to maintain the overall the Phase II budget. The Commission also determines that it will exclude any area funded through the rural broadband experiments from the Phase II competitive bidding process.

15. The Commission concludes that areas served by competitive eligible telecommunications carriers (ETCs) will be eligible for support in the rural broadband experiments. The Commission notes that it received a number of expressions of interest from competitive affiliates of rate-of-return carriers operating out of region in price cap territories, and it recognizes that these carriers may be interested in submitting rural broadband experiment proposals, alone or in partnership with other entities. The Commission is interested in learning the extent of interest among competitive ETCs to provide fixed voice and broadband services to the home with recurring support, using both wireline and wireless technologies.

16. The Commission has concluded that competitive ETCs awarded support through the Phase II competitive bidding process will cease to receive legacy phase-down support for those specific areas upon receiving their Phase II support. This rule will apply to participants in the rural broadband experiments, given the rural broadband experiments represent the first step of implementing a competitive bidding process for Phase II support in price cap territories. The Commission believes it is important to implement the measures that the Commission has already adopted for the Phase II competitive

bidding process to the extent possible in these experiments.

2. Applicant Eligibility

17. The Commission concluded in the *Tech Transitions Order* that it would encourage participation in the rural broadband experiments from a wide range of entities—including competitive local exchange carriers, electric utilities, fixed and mobile wireless providers, WISPs, State and regional authorities, Tribal governments, and partnerships among interested entities. The Commission was encouraged to see the diversity in the expressions of interest submitted by interested parties. Of the more than 1,000 expressions of interest filed, almost half were from entities that are not currently ETCs, including electric utilities, WISPs, and agencies of state, county or local governments.

18. The Commission reminds entities that they need not be ETCs at the time they initially submit their formal proposals for funding through the rural broadband experiments, but that they must obtain ETC designation after being identified as winning bidders for the funding award. As stated in the *Tech Transitions Order*, the Commission expects entities to confirm their ETC status within 90 days of the public notice announcing the winning bidders selected to receive funding. Any winning bidder that fails to notify the Bureau that it has obtained ETC designation within the 90 day timeframe will be considered in default and will not be eligible to receive funding for its proposed rural broadband experiment. Any funding that is forfeited in such a manner will not be redistributed to other applicants. The Commission concludes this is necessary so that it can move forward with the experiments in a timely manner. However, a waiver of this deadline may be appropriate if a winning bidder is able to demonstrate that it has engaged in good faith to obtain ETC designation, but has not received approval within the 90-day timeframe.

19. The Commission sought comment in the *Tech Transitions FNPRM* on whether to adopt a presumption that if a state fails to act on an ETC application from a selected participant within a specified period of time, the state lacks jurisdiction over the applicant, and the Commission will address the ETC application. Multiple commenters supported this proposal. The Commission now concludes that, for purposes of this experiment, if after 90 days a state has failed to act on a pending ETC application, an entity may request that the Commission designate it as an ETC, pursuant to section 214(e)(6).

Although the Commission is confident that states share our desire to work cooperatively to advance broadband, and it expects states to expeditiously designate qualified entities that have expressed an interest in providing voice and broadband to consumers in price cap areas within their states, the Commission also recognizes the need to adopt measures that will provide a pathway to obtaining ETC designation in situations where there is a lack of action by the state.

3. Three Types of Experiments

20. The \$100 million budget for the rural broadband experiments in price cap territories will be divided into three separate categories: \$75 million for projects meeting very high performance standards; \$15 million for projects meeting specified minimum performance standards that exceed the Commission's current standards; and \$10 million for projects dedicated to serving extremely high-cost locations. Below, the Commission outlines the performance standards that entities interested in participating in the rural broadband experiments must meet or exceed in order to be considered for funding in each category.

21. The Commission stated in the *Tech Transitions Order* that its focus for the rural broadband experiments was to deploy robust, scalable networks in rural areas not served by an unsubsidized competitor offering voice service and Internet access that delivers 3 Mbps downstream/768 kbps upstream. To test whether providers are willing and able to deliver services with performance characteristics in excess of the current minimum standards that price cap carriers accepting model-based support are required to offer to all funded locations, the Commission will require all recipients of funding in the rural broadband experiments to offer, at a minimum, at least one standalone broadband service plan more robust than the Commission's current standard of 4 Mbps downstream/1 Mbps upstream to all locations within the selected census blocks, with a specific amount of usage at a price no higher than the reasonable comparability benchmarks for voice service and broadband service, and that meets defined quality standards. The extent to which parties file formal proposals committing to meet these standards in the rural broadband experiments might provide information relevant for the decisions the Commission expects to make in the coming months regarding proposals set forth in the *Connect America Fund FNPRM*.

22. Given the number of providers that submitted expressions of interest for projects of significant size to deploy fiber to the premises, and to ensure that our budget permits the selection of several such projects to ensure diversity, the Commission makes the largest amount of funding—\$75 million—available for projects seeking to meet very high performance standards. These projects must propose to deploy a network capable of delivering 100 Mbps downstream/25 Mbps upstream, while offering at least one service plan that provides 25 Mbps downstream/5 Mbps upstream to all locations within the selected census blocks. Recipients must provide usage and pricing that is reasonably comparable to usage and pricing available for comparable wireline offerings (i.e., those with similar speeds) in urban areas, and latency no greater than 100 milliseconds (ms).

23. The Commission will make \$15 million available for projects where the provider would offer at least one service plan that provides 10 Mbps downstream/1 Mbps upstream to all locations within the selected census blocks. This service plan also must offer at least a 100 GB usage allowance, no more than 100 ms of latency, and meet the reasonable comparability benchmarks for the pricing of voice and broadband.

24. The Commission also is interested in learning more about the extent of provider interest in serving extremely high-cost census blocks, as defined by the Connect America Cost Model. The Commission will make \$10 million available for projects exclusively in such areas that propose to offer services delivering 10 Mbps downstream/1 Mbps upstream, with 100 GB of usage and a price that meets our reasonable comparability benchmarks. Projects seeking funding in this category must propose to serve all the locations within the extremely high-cost block or blocks on which the applicant bids. These projects also must propose to serve only extremely high-cost census blocks; a project will not become eligible for this category if it proposes to serve one extremely high-cost census block as part of a larger project to serve other eligible census blocks. The Commission expects to receive a number of creative proposals that will inform us as to the types of technologies that entities can most efficiently deploy to serve extremely high-cost areas, while still meeting the proposed minimum performance standards. For example, the Commission hopes to learn more about interest in the deployment of various fixed wireless solutions,

including broadband services using TV white space and/or hybrid solutions that combine fiber and fixed wireless technologies to offer broadband services in extremely high-cost areas.

25. Satellite providers that are interested in serving extremely high-cost locations may submit proposals for participation in the rural broadband experiments. The Commission recognizes, however, that these providers may not be able to satisfy the 100 ms latency standard that it establishes for the other two groups. Therefore, the Commission will use other metrics for voice quality in the context of these experiments. Specifically, any winning satellite provider may satisfy our requirements for quality of voice service by demonstrating it can provide voice service that meets a Mean Opinion Score (MOS) of four or greater.

D. Selection Methodology and Bidding Process

1. Selection Criteria

26. In the *Tech Transitions FNPRM*, the Commission sought comment on four types of selection criterion for the rural broadband experiments and proposed that cost-effectiveness should be the primary criteria in evaluating which applications to select. The Commission noted that one potential measure of cost-effectiveness is whether the applicant proposes to serve an area for an amount less than model-based support.

27. Based on further consideration and our review of the record, the Commission concludes that it should select winning bidders based on objective measures of cost-effectiveness, rather than using a more complicated scheme of weighting or scoring applications on multiple dimensions. Because the Commission has structured our selection process to choose experiments from three separate categories, it expects to select a diversity of projects in terms of geography and technologies. Recognizing unique challenges in serving Tribal lands, the Commission provides a bidding credit for entities that propose projects that will serve only Tribal census blocks, which will have the effect of making such projects more cost-effective relative to proposals from other entities. Rather than using subjective criteria to evaluate the financial and technical qualifications of each applicant before selection, the Commission requires selected applicants to submit additional information demonstrating that they have the technical and financial qualifications to successfully complete

their proposed projects within the required timeframes.

28. The Commission concludes that it should use cost-effectiveness to select applications, and it will calculate this measure in two ways for different categories of applications. As detailed below, for those applications proposing to serve census blocks identified by the Connect America Cost Model as eligible for Phase II support, the Commission will compare requested amounts to model-based support amounts. For applications proposing to serve only census blocks the model identifies as “extremely high-cost,” for which there is no model-determined level of support, the Commission will select applications based on the lowest-cost per location. The Commission finds that using these objective, straightforward, and easily measurable criteria will best meet our goals to efficiently distribute support in these experiments and to test on a limited scale a competitive bidding process that can be implemented quickly to inform our decisions regarding how to design the Phase II competitive bidding mechanism. The Commission sought comment in the *Tech Transitions FNPRM* on ways to leverage non-Federal governmental sources of funding, but the record was insufficient for us to determine how best to implement measures that would create incentives for non-Federal governmental entities to assist in advancing universal service. The Commission seeks more focused comment in the concurrently adopted FNPRM on the use of bidding credits in the Phase II competitive bidding process that will occur after the offer of model-based support to price cap carriers.

29. Many commenters agree that cost-effectiveness should be the primary, or even only, criterion in evaluating which applications to select, although some commenters advocate for an approach that would select winning bidders based on the lowest cost per location without comparison to model-based support. The Commission concludes that it should use cost-effectiveness—defined as requested dollars per location divided by model-based support per location—to select applications in categories one and two. The Commission recognizes that it could potentially extend the availability of broadband-capable networks to more locations if it were to use only lowest-cost per location to select projects in all three groups. In addition to using our limited budget for these rural broadband experiments efficiently, however, the Commission also hopes to select projects in a variety of geographic areas. Using lowest-cost alone would likely

result in selecting proposals for experiments with similar cost characteristics—specifically, those areas that just barely meet the threshold for being “high-cost.” By selecting winning bidders based on the ratio of requested support to support calculated by the cost model, the Commission expects to award funding to projects in areas with varying cost profiles, with greater geographic diversity, which will be informative to our consideration of the impact of technology transitions in different parts of the country. Moreover, comparing the amounts bid to the model-determined support will enable us to test the use of the cost model for purposes of setting reserve prices for future implementation of the Phase II competitive bidding process.

30. Some commenters suggest that the Commission should measure cost-effectiveness in relation to broadband speeds. The Commission concludes that the approach it adopts today, however—setting aside the largest portion of our budget for those projects proposing to meet very high performance standards—is a more straightforward method of encouraging the deployment of robust, scalable networks in areas that would be eligible for Phase II support and testing the extent of interest in deploying such networks in these areas. Directly including robustness as a selection criterion would increase the complexity of the competitive bidding process by requiring the Commission to determine how much of a bidding credit should be provided for proposals offering service at different speeds.

31. For purposes of evaluating cost-effectiveness in comparison to the model, among applicants in each of the first two experiment categories, the Commission will calculate the ratio of requested support per location to model-based support per location in the census blocks the applicant proposes to serve. First, the Commission will divide the total amount of support requested for each proposal by ten so it can compare proposals to annual model-based support amounts. Then the Commission will calculate each proposal’s requested support per location and divide that number by the model-based support per location. Using these ratios, the Commission will rank the proposals from the lowest to highest in each category—where the lowest ratio indicates the greatest cost-effectiveness—and select those projects with the lowest ratio within the \$75 million budget for the first category of projects, and within the \$15 million budget for the second category of projects.

32. As discussed above, support recipients are required to offer the requisite service to the total number of locations in the census blocks that they propose to serve, but may choose to add some locations in adjacent census blocks with costs above the extremely high-cost threshold. The Commission anticipates that there may be areas in which a provider can cost-effectively provide service in extremely high-cost census blocks that are adjacent to funded census blocks. To encourage entities to do so, the Commission will permit applicants that commit to serve locations in extremely high-cost census blocks (which receive no model-based support) to add these locations to the calculation of their requested support per location for the project. The effect of including these extremely high-cost locations would be to lower the support per location of the project and improve the overall cost-effectiveness.

33. For purposes of evaluating proposals in category three, the Commission will calculate the cost per location, and rank these applications on a dollar requested per location basis, from lowest to highest. The Commission will select projects based on the lowest cost per location, until the budget is exhausted. Parties that submit proposals for both category one or two along with a proposal for category three may identify their category three proposal as contingent on their being a winning bidder for a category one or two proposal. In that case, a party that would otherwise be selected in category three based on its cost-effectiveness score, but that fails to win for a category one or two proposal, would not win; instead, the next most cost-effective proposal in category three would be selected.

34. No census block will receive support from more than one proposal. Accordingly, once a proposal has been selected, any other proposals that would cover any of the census blocks in the selected proposals will no longer be eligible. The Commission does not anticipate that our evaluation criteria will result in ties among winners, but if two or more applications result in identical rankings of cost-effectiveness, the Commission will select the project that proposes to serve the most locations if the budget would not permit funding all the tied proposals. If more than one tied proposal includes the same census block, the Commission would select the project that proposes to serve the most locations. In the unlikely event that tied and overlapping proposals serve the identical number of locations, the Commission will select the supported project randomly.

2. Measures To Ensure Diversity of Projects

35. Given our interest in testing how a variety of entities use Connect America funds in various geographic locations, and deploy different types of technologies, the Commission finds that it will be advantageous to award support to a diverse group of projects within the \$100 million budget. Below, the Commission adopts certain measures that aim to ensure that the projects funded through the rural broadband experiments bring robust broadband networks to the widest range of price cap areas possible.

36. *Funding Limits.* There has been a wide variety in the funding amounts requested by interested entities. To preclude one entity or one project from exhausting the entire budget, the Commission places limits on the amount of funding that each project and each entity can receive. With these limits, the Commission balances our interest in permitting multiple projects and entities to receive funding, with our interest in learning from projects that request varying levels of support. By adopting these per project and per entity limits and deciding to award support based on cost-effectiveness compared to the model determined support, the Commission expects that the projects that ultimately win support will be geographically diverse.

37. First, the Commission adopts project limits for each experiment category it adopts above to ensure that it awards support to multiple projects within each category. The Commission places a limit of \$20 million per project for those projects submitted to the very high performance standards category, a limit of \$7.5 million per project for those projects submitted to the minimum performance standards category, and a limit of \$5 million per project for those projects submitted to the extremely high-cost areas category. The Commission chooses these numbers to ensure that it is able to select at least two projects in each category, to provide greater diversity.

38. Second, the Commission adopts an overall limit of \$20 million per entity, including its affiliates. Each entity and its affiliates will be precluded from being awarded more than \$20 million in support across all three experiment categories. This limit also applies in situations where an entity is in more than one consortium.

39. *Service to Tribal Lands.* In the *Tech Transitions FNPRM*, the Commission sought comment on including as a selection criterion whether applicants propose to offer

high-capacity connectivity to Tribal lands. Rather than a separate selection criterion that the Commission would have to measure against cost-effectiveness, it now concludes that using a bidding credit is more consistent with the type of objective selection criteria it is adopting for the experiments and the Commission's precedent. This is consistent with our *Connect America Fund FNPRM*, which sought comment on using bidding credits for service to Tribal lands.

40. For the purposes of the rural broadband experiments, the Commission adopts a 25-percent credit for those seeking support for proposed experiments that serve only Tribal census blocks. The credit will effectively reduce the bid amount of qualifying experiments by 25 percent for purpose of comparing it to other bids, thus increasing the likelihood that experiments serving Tribal blocks will receive funding. This credit will be available with respect to eligible census blocks located within the geographic area defined by the boundaries of the Tribal land. As noted above, the Commission directs the Bureau to release the list of census blocks that will be eligible for this credit in the rural broadband experiments within 15 days of releasing this Order. Because the Commission is focused on swiftly implementing these experiments, it will not entertain any proposals to modify this list.

3. Mechanics of the Bidding Process

41. To participate in the rural broadband experiments, entities must submit a formal application to the Commission. The formal application must be submitted no later than 90 days from the release of the Order. As part of this formal application, entities will be required to submit confidential bids requesting a certain amount of support to serve specified census blocks. Additionally, entities will be required to provide information regarding any agreements or joint bidding arrangements with other parties, disclose any ownership interests in or by Commission-regulated companies, declare whether their project will serve only Tribal census blocks, submit a proposal containing basic information that would be informative to the general public and will be released publicly only if they win support, and certify that they meet certain threshold requirements, including being in compliance with all the statutory and regulatory requirements and being financially and technically capable of meeting the required public interest

obligations in each area they seek support.

42. The Commission requires all entities submitting proposals to utilize a FCC Registration Number (FRN) to ensure that each application has a unique identifier. Any entity that currently does not have a FRN must first register with the Commission's "Commission Registration System" (CORES), upon which it will be assigned a FRN. In the case of multiple entities forming a partnership to submit a single bid, the Commission requires only one entity in the partnership to be registered with a FRN.

43. Entities must specify the type of project for which they are submitting a proposal (i.e., very high performance, minimum performance, or extremely high-cost). Entities may choose to submit multiple proposals in the same category, as well as different proposals in multiple categories. However, in determining who is the winning bidder for funding in each category, proposals will only be compared to proposals in the same category, i.e., a proposal to serve census blocks with very high performance service will only be compared against other proposals in that category if the applicant chose not to submit the proposal in another category. Proposals that do not meet the criteria for selection in one category will not be automatically considered in another group. For example, if an entity proposes to serve certain census blocks with very high performance service, but is not a winning bidder for funding in that category, that project will not be considered for funding in the minimum performance category, even if it might be a winning bidder for that category.

44. Entities must provide the census block IDs for each census block they propose to serve, the number of eligible locations determined by the model in each of those blocks, and the total amount of support they request. The Commission notes that, even if an entity is proposing to serve the entire census tract, it must list the IDs of all the census blocks within that tract. As noted above, the Bureau will release the list of eligible census blocks, the associated number of locations eligible for funding in each block, and the associated amount of support by block. The amount of funding made available for any experiment will not exceed the amount of model-calculated support for the given geographic area. Applications with a total request for funding that exceeds the model-based support calculation will not be considered. Therefore, the Commission expects entities to consult the list released by the Bureau to ensure that bids on any

group of census blocks do not exceed the amount of support calculated by the model to serve those census blocks.

45. The formal proposal should include background information on the applicant and its qualifications to provide voice and broadband service; a description of the proposed project, service area, planned voice and broadband service offerings, and technology to be used; and the number of locations, including community anchor institutions, within the project area. As the Commission noted in the *Tech Transitions Order*, rural areas are home to a higher proportion of low-income Americans. The Commission seeks to learn how providers intend to serve low-income consumers if they receive rural broadband experiment support. Thus, the formal proposal should include a description of what Lifeline services the applicant intends to offer if awarded support, whether it will have a broadband offering for low-income consumers, and whether it will permit qualifying consumers to apply the Lifeline discount to bundled voice and data services.

46. The information in the formal proposal will not be used to select winning bidders; as discussed above, winning bidders will be selected solely on their numerical score. All bids for the rural broadband experiments will be considered confidential, and bidders should not disclose their bids to other bidders. However, once the Bureau has issued a public notice listing the winning bidders, the winning bidders' proposals will be released to the public. The Commission concludes that making the winning bidders' proposals public will provide an increased level of transparency and enable parties outside the process to hold winning bidders publicly accountable for not fulfilling the requirements of the experiments. However, all other proposals will remain confidential, pending the completion of the Phase II competitive bidding process, in order to prevent these proposals from affecting a potential bidder's behavior in the Phase II competitive bidding process.

4. Post-Selection Review

47. The Bureau will issue a public notice identifying the winning bidders, as specified above, that may be authorized to receive support and the list of census blocks included in their proposed projects, which are presumptively unserved by an unsubsidized competitor. As the Commission determined in the *Tech Transitions Order*, the Bureau then will conduct a challenge process similar to the process it used for determining

eligible areas for model-based support. To the extent that a challenge is granted in whole or in part, funding for those locations will be adjusted proportionately.

48. *Technical and Financial Review.* The Bureau will determine whether each selected applicant has demonstrated that it has the technical and financial qualifications to successfully complete the proposed project within the required timeframes and is in compliance with all statutory and regulatory requirements for the universal service support that the applicant seeks. Commission staff will perform a review to ensure that the selected applicants meet our expectations for technical and financial capability to conduct an experiment before any support is provided.

49. The Commission has recognized network security as an imperative in technology transitions. For broadband networks across the nation to be considered advanced, robust, and scalable, they must also be secure and resilient in the face of rapidly evolving cybersecurity threats. Here, the Commission seeks to promote the sustainability of rural broadband through early planning to incorporate effective cybersecurity risk management measures. The Commission commits to support entities selected for these rural broadband experiments with training resources and guidance to that end. Incorporating adequate security early in the design and throughout the deployment of broadband networks is more effective than addressing security problems retrospectively, and ultimately lowers costs by hardening networks against preventable outages and catastrophic failures that could threaten the viability of smaller and/or new market entrants in rural broadband. Small providers in diverse service areas play a key role because any point of weakness in today's interconnected broadband ecosystem may introduce risk into the entire network of interconnected service providers. Security improvements reduce risk to all interconnected service providers, their customers and the nation as a whole. The support that the Commission commits in this Order to provide to selected applicants is limited to sharing information and resources regarding cybersecurity risk management measures that the selected applicants may find beneficial as they plan their deployments. No applicant will be required to make changes to its network design or infrastructure based on such measures, nor will any applicant be rejected for not addressing cyber risk management best practices in

its proposal. The Commission's engagement with selected entities should help inform CSRIC's ongoing efforts to remove cybersecurity barriers for small companies competing in the broadband services market, but the Commission will not share any applicant's proprietary or sensitive information related to cybersecurity, or any cybersecurity information that would identify the applicant, with CSRIC or other companies or government agencies.

50. Within 10 business days of public notice of winning bidders, the Commission requires all winning bidders to provide the most recent three consecutive years of audited financial statements, including balance sheets, net income, and cash flow, and to submit a description of the technology and system design used to deliver voice and broadband service, including a network diagram, which must be certified by a professional engineer. Winning bidders proposing to use wireless technologies also must provide a description of spectrum access in the areas for which the applicant seeks support. Within 60 days of public notice of winning bidders, the Commission requires all winning bidders to submit a letter from an acceptable bank committing to issue an irrevocable stand-by original letter of credit (LOC) to that entity. Finally, each selected applicant is required to provide within 90 days of public notice of winning bidders appropriate documentation of its ETC designation in all the areas for which it will receive support and certify that the information submitted is accurate. Once the Bureau has determined that the entity is financially and technically qualified to receive experiment support and that the LOC commitment letter is sufficient, it will release a public notice stating that the entity is ready to be authorized for support. Within 10 business days of this public notice, the Commission requires that the winning bidder submit an irrevocable stand-by original LOC that has been issued and signed by the issuing bank along with the opinion letter from legal counsel that it describes below. Once the Universal Service Administrative Company (USAC) has verified the sufficiency of the LOC and the opinion letter, the Bureau will issue a public notice authorizing the entity to receive its first disbursement.

51. *Requirements for Letters of Credit.* The Commission requires a winning bidder to secure an irrevocable stand-by original LOC for its winning project before support will be disbursed. The Commission's decision to require entities to obtain a LOC is consistent

with the requirements it has adopted for other competitive bidding processes the Commission has conducted to distribute Connect America funds, where both existing providers and new entrants were required to obtain LOCs. The LOC must be issued in substantially the same form as set forth in the model LOC provided in Appendix A of this Order, by a bank that is acceptable to the Commission. As explained below, if an entity fails to meet the terms and conditions of the rural broadband experiments after it begins receiving support, including the build-out milestones and performance obligations the Commission adopts in this Order, and fails to cure within the requisite time period, the Bureau will issue a letter evidencing the failure and declaring a default, which letter, when attached by USAC to a LOC draw certificate, shall be sufficient for a draw on the LOC to recover all support that has been disbursed to the entity. Once the recipient's support term has ended, the LOC must remain open and renewed to secure the amount of support disbursed for 120 days to allow time to validate that the rural broadband experiment recipients have met the experiment's public service obligations and build-out milestones.

52. As the Commission found when it established Mobility Fund Phase I, LOCs are an effective means of securing our financial commitment to provide Connect America support. LOCs permit the Commission to protect the integrity of universal service funds that have been disbursed and immediately reclaim support that has been provided in the event that the recipient is not using those funds in accordance with the Commission's rules and requirements to further the objectives of universal service. Moreover, LOCs have the added advantage of minimizing the possibility that the support becomes property of a recipient's bankruptcy estate for an extended period of time, thereby preventing the funds from being used promptly to accomplish our goals. These concerns are relevant to both new entrants and established providers.

53. While our existing accountability measures help ensure that Connect America funds are being used to deploy or sustain broadband and voice-capable networks, the Commission concludes that additional measures are necessary to protect the ability of the Commission to recover support from parties that fail to perform. The Commission required winners of the Mobility Fund Phase I and Tribal Mobility Phase I auctions to obtain LOCs, and it sees no reason to depart from this practice for the rural broadband experiments. The

Commission continues to view them as beneficial and our experience has shown that winning bidders are able to obtain LOCs.

54. *LOC Opinion Letter.* Consistent with our requirements for Mobility Fund Phase I and Tribal Mobility Fund Phase I, winning bidders must also submit with their LOCs an opinion letter from legal counsel. That opinion letter must clearly state, subject only to customary assumptions, limitations, and qualifications, that in a proceeding under the Bankruptcy Code, the bankruptcy court would not treat the LOC or proceeds of the LOC as property of the account party's bankruptcy estate, or the bankruptcy estate of any other rural broadband experiment recipient-related entity requesting issuance of the LOC under section 541 of the Bankruptcy Code.

55. *Issuing Bank Eligibility.* The LOCs for winning bidders must be obtained from a domestic or foreign bank meeting the requirements adopted here for purposes of the rural broadband experiments. The criteria the Commission adopts are largely the same as the requirements the Commission adopted for Mobility Fund Phase I and Tribal Mobility Fund Phase I, although it adopts several modifications to enlarge the potential pool of eligible banks for purposes of these experiments. First, the Commission requires that for U.S. banks, the bank must be among the 100 largest banks in the U.S. (determined on the basis of total assets as of the end of the calendar year immediately preceding the issuance of the LOC) and must be insured by the Federal Deposit Insurance Corporation (FDIC) and for non-U.S. banks, the bank must be among the 100 largest non-U.S. banks in the world (determined on the basis of total assets as of the end of the calendar year immediately preceding the issuance of the LOC, determined on a U.S. dollar equivalent basis as of such date). The Commission expands the pool of eligible banks from the top 50 to the top 100 banks for purposes of these rural broadband experiments because it expects the projects to be small in scale, and thus drawing on the LOC is unlikely to exhaust the assets of any bank in the top 100. The Commission has also seen through our experience with Mobility Fund Phase I and Tribal Mobility Fund Phase I that entities have used a number of banks. Because the Commission expects that a number of smaller entities will be winning bidders and may not have established relationships with some of the largest banks, for purposes of these experiments it finds that it is beneficial

to increase the number of options from which they can choose. The Commission also requires that the selected U.S. bank have a credit rating issued by Standard & Poor's of BBB- or better (or the equivalent from a nationally recognized credit rating agency). For non-U.S. banks, the Commission requires that the bank has a branch in the District of Columbia or other agreed-upon location in the United States, has a long-term unsecured credit rating issued by a widely-recognized credit rating agency that is equivalent to an BBB- or better rating by Standard & Poor's, and that it issues the LOC payable in United States dollars. By allowing banks to have a BBB- rating instead of an A- rating, the Commission will enlarge the pool of eligible issuing banks, without significantly increasing risk to the universal service fund.

56. To provide more flexibility, the Commission also concludes that winning bidders for the rural broadband experiments may obtain a LOC from agricultural credit banks in the United States that serve rural utilities and are members of the United States Farm Credit System (which is modeled after the FDIC). The Commission finds that Farm Credit System Insurance Corporation (FCSIC) insurance provides protection that is equivalent to those indicated by holding FDIC-insured deposits. Thus, the agricultural credit bank must have its obligations insured by the FCSIC. The agricultural credit bank must also meet the other requirements that the Commission has adopted for U.S. banks, including that they have a long-term unsecured credit rating issued by Standard & Poor's of BBB- or better (or an equivalent rating from another nationally recognized credit rating agency), and that their total assets are equal to or exceed the total assets of any of the 100 largest United States banks. This will permit rural broadband experiment recipients to obtain LOCs from, for example, CoBank, a bank with which many small rural carriers have a relationship.

57. If a recipient has been issued a LOC from a bank that is no longer able to honor the letter of credit at any point during its support term, that recipient will have 60 days to secure a LOC from another issuing bank that meets our eligibility requirements. The Commission also reserves the right to temporarily cease disbursements of monthly support until the recipient submits to us a new LOC that meets our requirements.

58. *Value of LOC.* When a winning bidder first obtains a LOC, it must be equal to the amount of the first

disbursement. Before the winning bidder can receive additional disbursements, it must modify or renew its LOC to ensure that it is valued at the total amount of money that has already been disbursed plus the amount of money that is going to be provided for the next disbursement. To reduce administrative costs, a recipient may choose to renew its LOC on an annual rather than monthly basis so that it is valued at the amount of money to be disbursed in the coming year plus the total disbursements it has received so far.

59. *Procedure for Drawing on LOC.* As described below, the Bureau will notify an entity that it has failed to comply with the terms and conditions of the rural broadband experiments, including public interest obligations and build-out milestones, and will provide an opportunity for cure before issuing a finding of default. Once the Bureau has determined that the entity has defaulted, the Bureau Chief will send a letter to the entity to notify it of the default. USAC will then issue the form letter attached as Appendix A of this Order to the issuing bank with the Bureau Chief's letter attached, initiating the draw on the LOC.

60. *Costs of Obtaining LOCs.* Now that the Commission has experience with LOCs in the Mobility Fund Phase I and Tribal Mobility Fund Phase I auction, it is confident that winning bidders will be able to secure LOCs. The Commission notes that no winning bidders defaulted in Mobility Fund Phase I and Tribal Mobility Fund Phase I auctions because they were unable to secure a LOC. The Commission recognizes that banks charge fees for obtaining LOCs and also may charge renewal fees. But the Commission finds that the advantages of LOCs in ensuring that Connect America support can quickly be reclaimed to protect the Universal Service Fund, and that the support is protected from being included in a bankruptcy estate, outweigh the potential costs of LOCs for the winning bidders. And as the Commission noted in the *USF/ICC Transformation Order*, 76 FR 73830, November 29, 2011, LOCs are regularly used in the course of business, and companies that use existing lenders are able to use multiple forms of financing. Moreover, requiring that winning bidders obtain LOCs that only secure the sum of money that has been (and soon will be) disbursed will help alleviate the cost of the LOCs. The Commission also notes that applicants can factor in the costs of LOCs when submitting their bids.

61. *Applicability to All Winning Bidders.* The Commission's paramount objective is to establish strong safeguards to protect against misuse of the Connect America Fund. The Commission concludes that requiring all entities to obtain a LOC is a necessary measure to ensure that it can recover support from any recipient that cannot meet the build-out obligations and public service obligations of the rural broadband experiments. The Commission also agrees with those commenters that argue that requiring all recipients to obtain a LOC will ensure that all recipients are subject to the same default process if they do not comply with the experiments' terms and conditions.

62. The Commission is not persuaded by arguments that it should only require certain entities to obtain LOCs, particularly recipients that have not met the Commission's rules in the past or cannot meet a specified financial threshold. Compliance with existing universal service rules has no bearing on whether an entity necessarily is financially qualified to undertake the obligations of the rural broadband experiments. Moreover, it is possible that some of the winning bidders for the rural broadband experiments may not have participated in Commission programs before. The Commission finds that a LOC provides the safeguard of allowing the Commission to immediately take back support if it turns out that the recipient fails to meet the requirements. The requirement will also impress upon all entities participating in the experiments the significant undertaking to which they are committing.

63. *Tribal Nations and Tribally-Owned Applicants.* Based on the Commission's experience in implementing LOCs for Mobility Fund Phase I and Tribal Mobility Fund Phase I, it recognizes there may be a need for greater flexibility regarding LOCs for Tribally-owned or -controlled winning bidders. In many situations, requiring a LOC from Tribally-owned entities may be impractical because Tribal Nations are subject to various somewhat unique economic challenges, including the inability to levy income taxes on their citizenry and to collateralize their lands. When title to Tribal lands is vested in the United States or such lands are subject to trust restrictions against encumbrances, Tribal Nations are not in a position to provide them as collateral for such a letter of credit. The Commission finds that such situations with respect to Tribal Nations are best handled on a case-by-case basis through the waiver process.

64. If any Tribal Nation or Tribally-owned or -controlled applicant for the rural broadband experiments is unable to obtain a LOC, it may file a petition for a waiver of the LOC requirement. Waiver applicants must show that the Tribal Nation is unable to obtain a LOC because of limitations on the ability to collateralize its real estate, that rural broadband experiment support will be used for its intended purposes, and that the funding will be used in the best interests of the Tribal Nation and will not be wasted. Tribal applicants could establish this showing by providing, for example, a clean audit, a business plan including financials, provision of financial and accounting data for review (under protective order, if requested), or other means to assure the Commission that the rural broadband experiment is a viable project. Given the number of expressions of interest filed by Tribally-owned or -controlled entities to serve areas within price cap territories, the Commission concludes that it will be manageable to address this situation on a waiver basis if such entities become winning bidders.

65. *Due Process Concerns.* By virtue of entering into a LOC, the recipient has notice that the Bureau may choose to draw on the LOC if it finds that the recipient has defaulted on its rural broadband experiment obligations or it fails to timely replace an expiring LOC. Because the experiments are purely voluntary, participants that find that these terms and conditions are too burdensome can choose not to participate. By filing an application to be authorized for support with the Commission, an applicant knowingly accepts that the Bureau can exercise its right to recover distributed support by drawing on the LOC in the event of non-compliance. The Commission also adopts a process whereby recipients will have the opportunity for cure if they later come into compliance with the terms and conditions of the rural broadband experiments.

66. Instead of having to bring a legal action against the recipient if the rural broadband experiment obligations are not met after the time for cure has passed, the LOC allows the Bureau immediately to reclaim the support. A LOC merely shifts the risk associated with non-compliance from the Commission to the recipient. To the extent that recipients believe that the Bureau has unnecessarily drawn on their LOC, they will have the opportunity to take recourse through the regular Commission review process.

67. Moreover, the Commission is not persuaded that LOCs raise due process concerns. For a LOC, USAC must

present the proper draw documentation to the issuing bank demonstrating, *inter alia*, that the terms and conditions of the rural broadband experiments have not been met. The issuing bank will then provide USAC with a sum of money equal to the value of the LOC. As the Commission discusses above, the Bureau will release a letter finding default before USAC draws on the LOC. Providing for a lengthy process that would permit recipients to dispute the Bureau's findings of default prior to seeking recovery would unnecessarily hold up the process of recovering support disbursed for these rural broadband experiments.

E. Conditions for Rural Broadband Experiment Support

68. In the *Tech Transitions Order* the Commission stated that funding for the rural broadband experiments will be "subject to the applicable requirements of sections 214 and 254 of the Act and will be conditioned on complying with all relevant universal service rules that the Commission has adopted or may adopt in the future in relevant rulemaking proceedings. . . ." The Commission also sought comment on whether it should adopt any rules or requirements specific to the rural broadband experiments. Here, the Commission adopts several conditions that winning bidders must meet to receive rural broadband experiment support. The conditions the Commission adopts for the purposes of these limited experiments are tailored for ensuring that experiment funds are used for their intended purpose of deploying robust networks to high-cost areas; detecting waste, fraud, and abuse; and permitting us to quickly gather data and other information about the experiments that the Commission can leverage when making key policy decisions regarding both universal service and technology transitions.

1. Build-Out Requirements

69. The Commission requires winning bidders to meet certain build-out requirements during their support term. Consistent with the build-out requirements the Commission has already adopted for the Connect America Fund, it finds that establishing clearly defined build-out requirements will ensure that recipients remain on track to meet their public service obligations and that Connect America funds are being used to deploy robust networks consistent with their intended purpose.

70. *Build-Out Requirements for all Recipients.* As the Commission discusses above, all recipients of rural

broadband support will receive support in 120 equal monthly disbursements over a 10-year support term, consistent with the support term it has adopted for the Phase II competitive bidding process. The support term will begin with the first disbursement of support after the entities have been notified that they are the winning bidders and that they have met the requirements outlined above. During this support term, the recipients will be required to meet interim build-out requirements consistent with the build-out requirements the Commission has adopted generally for recipients of Connect America Phase II funding. By the end of the third year, the recipients must offer service meeting the public service obligations the Commission adopted for the relevant experiment category to at least 85 percent of the number of required locations and submit the required certifications and evidence. By the end of the fifth year, the recipients must offer service meeting the public service obligations the Commission adopted for the relevant experiment category to 100 percent of the number of required locations and submit the required certifications and evidence. Recipients must comply with the terms and conditions of rural broadband experiment support for the full 10-year support term.

71. *Accelerated Disbursement Option.* Although the Commission adopts the above build-out requirements for recipients of the rural broadband experiments to conform to our existing requirements for Phase II, based on our review of the expressions of interest, it appears that some entities may be in a position to complete deployment in the 18 to 24 month timeframe. To provide an additional incentive for parties to build out their projects quickly so that the Commission can learn from these deployments and leverage that knowledge when making policy decisions regarding technology transitions, it also provides the option of accelerating disbursement of support for winning bidders in the experiments for those entities that commit to deploying to at least 25 percent of the requisite number of locations within the first 15 months. Entities will be required to indicate whether they are electing this option when they submit their application. If parties elect this option, the Commission will advance 30 percent of their support upfront, at the time they are first authorized to receive funding; the remaining 70 percent will be provided in 120 equal monthly installments over the 10-year term. Parties that elect this option will be

required to obtain a LOC for the 30 percent advance payment before funding is authorized. To ensure that these funds are being used in accordance with the objectives of the rural broadband experiments, the Commission requires that recipients choosing this option deploy to 25 percent of the number of required locations and submit the required certifications and evidence within 15 months of their first disbursement of support. These recipients then must meet the same build-out obligations that are required of all recipients of rural broadband experiment support (i.e., 85 percent of locations within three years and 100 percent of locations within five years).

2. Accountability Requirements

72. In the *Tech Transitions Order*, the Commission noted that rural broadband experiment support will be conditioned on complying with all relevant universal service fund rules including reporting requirements and audits. Here, the Commission provides more details regarding the framework for accountability that it adopts for recipients of the rural broadband experiments. The reports, certifications, and other accountability measures the Commission adopts serve a dual purpose. First, a framework for accountability “is critical to ensure appropriate use of high-cost support” and allows the Commission to detect and deter waste, fraud, and abuse. Second, the framework the Commission adopts below will permit us to quickly gather data about how the experiment funds are being put to use, which will inform policy decisions it ultimately makes for Phase II and our other universal service programs.

73. *Annual Reports*. All recipients of Connect America support are required to file an annual report pursuant to § 54.313 of the Commission’s rules by July 1st of each year. This requirement also applies to recipients of support in the rural broadband experiments. The Commission finds there is good cause, however, to waive on our own motion § 54.313(a)(1) of the Commission’s rules for recipients of rural broadband experiment support. Because the Commission adopts other requirements for the rural broadband experiments recipients that will ensure that it will be kept apprised of their build-out progress, the Commission finds that it is unnecessary to require these entities to file a five-year service quality plan.

74. As the Commission requires of price cap carriers accepting model-based support, it also requires participants in the rural broadband

experiments to demonstrate that the services they offer in their project areas meet the Commission’s latency standard. The participants must submit a certification with each annual report certifying that 95 percent or more of all peak period measurements (also referred to as observations) of network round trip latency are at or below 100 ms. Recipients may use the approach adopted in the Bureau’s *Phase II Service Obligations Order*, 78 FR 70881, November 27, 2013, to measure latency.

75. In addition, because these rural broadband experiments represent the first implementation of Phase II of the Connect America Fund, the Commission requires participants in the experiments to comply with the existing requirement for Phase II recipients of providing in their annual reports the number, names, and addresses of community anchor institutions to which the recipients newly began providing access to broadband service in the preceding year. The Commission concludes this requirement will be a valuable way to monitor how the experiment recipients are engaging with community anchor institutions, and learn how the networks supported by the experiments will impact anchor institutions and the communities they serve.

76. The Commission will also require recipients to file build-out information with their reports. This requirement will enable us to gather data faster on how the geographic and demographic characteristics of certain rural areas affect how experiment recipients build their networks. This requirement will also help us monitor recipients’ progress toward meeting their build-out requirements and that experiment funds are being used for their intended purpose. Specifically, the Commission requires all recipients of the rural broadband experiments to file with their annual reports evidence demonstrating to which locations they have deployed facilities. This information must be current as of the June 1st immediately preceding the July 1st deadline. Recipients must also submit evidence with the report that demonstrates they are meeting the relevant public service obligations. For instance, recipients may submit marketing materials with their reports that show the voice and broadband packages that are available to each location that meet the relevant public service obligations. The materials must at least detail the pricing, offered broadband speed, and data usage allowances available in the relevant geographic area.

77. To ensure that rural broadband experiment funds are being used for their intended purposes, the

Commission also finds that it would be helpful to monitor the recipients’ progress in deploying their networks prior to the deadline for the first annual report, which it anticipates will be July 2016. Thus, the Commission will require all recipients to file an interim report on the November 1st after they receive their first disbursement. This report will only be filed this one time and must describe the status of their project (i.e., whether vendors have been hired, permits have been obtained, construction has begun) and include evidence demonstrating which locations (if any) that the recipients have built out to in their project areas where the recipient is offering at least one voice service and one broadband service that meets the public service obligations adopted above for the relevant experiment category. To the extent locations are newly served by the time of this interim report, recipients must also submit evidence with the report as described above that demonstrates they are meeting the relevant public service obligations, including a certification that demonstrates the service they offer complies with the Commission’s latency requirements. This information should be current as of the September 30th immediately preceding the November 1st deadline. Because this is information that recipients will already need to collect to certify compliance with their build-out requirements, the value to the Commission in being able to gather this data on a more frequent basis outweighs the burden that one additional report will impose on experiment recipients.

78. *Certifications*. Like all recipients of Connect America support, all rural broadband experiment recipients that have been designated as ETCs by the Commission are required to file an annual certification pursuant to § 54.314 of the Commission’s rules stating that “all federal high-cost support provided to such carrier was used in the preceding calendar year and will be used in the coming calendar year only for the provision, maintenance, and upgrading of facilities and services for which the support is intended.” If an entity selected for a rural broadband experiment is designated an ETC by a state, that state must file this certification on behalf of the entity.

79. The Commission also requires experiment recipients to certify when they have met the build-out requirements defined above. All recipients must submit a certification to the Commission by the end of their third year of support that they offer service to at least 85 percent of their required number of locations with the required level of service and will need

to submit a certification by the end of their fifth year of support that they offer service to 100 percent of their required number of locations with the required level of service. Additionally, recipients that opt to receive 30 percent of their support upfront must submit a certification to the Commission stating that they have met their 25 percent build-out requirement within 15 months of the first disbursement. With these certifications, all recipients must present the same build-out information that must be included in their annual reports that the Commission describes above: evidence demonstrating that they have deployed facilities to the required number of locations and evidence that demonstrates compliance with the relevant public service obligations, including a certification demonstrating compliance with the Commission's latency requirement. The Commission expects to use a variety of methods to verify that recipients of support are in fact meeting the terms and conditions of the rural broadband experiments, including verification of the build-out evidence that they will submit with their annual reports and certifications.

80. *Compliance Reviews.* The Commission reiterates that all recipients of rural broadband experiment support are subject to compliance reviews and other investigations so that it can detect and deter waste, fraud, and abuse, and ensure that rural broadband experiment support is being used for its intended purpose.

81. *Record Retention.* The Commission also reiterates that rural broadband experiment recipients are subject to the 10 year record retention requirement adopted in the *USF/ICC Transformation Order*. This requirement will ensure that documents related to the experiments are available to facilitate USAC audits and other oversight measures.

3. Data Gathering

82. When adopting the service-based experiments, the Commission noted that "[t]he need for quality data regarding the effect on customers of adopting next generation technologies is perhaps greater now than ever before," and held that it intended that the service-based experiments would be "open data" experiments. In the *Tech Transitions Order*, the Commission sought comment on whether issues discussed in the context of the service-based experiments should also be addressed in the rural broadband experiments. The Commission finds that collecting data from the rural broadband experiments would similarly help them answer some of the key policy questions they

identified in the *Tech Transitions Order*. The Commission therefore requires that as a condition of receiving funding in the rural broadband experiments, recipients cooperate with the Commission in any efforts to gather data that may help inform future decisions regarding the impact of technology transitions on achievement of our universal access objectives.

83. As the Bureau reported at the Commission's open meeting on June 13, 2014, a competitive procurement process is underway to select a third party data evaluator to assist the Commission in collecting and analyzing data in connection with service-based experiments and other technology transitions contexts. This third party will be working with the Bureau to develop a research methodology using, among other things, surveying techniques. The Commission believes surveys could be useful in the context of the rural broadband experiments. For example, the issues to be surveyed might include consumer purchasing decisions, speed of adoption of new broadband services, service usage, and customer satisfaction with fixed wireless compared to alternatives, both landline and satellite. To minimize the burden on rural broadband experiment recipients, the Commission expects that they would need only to provide information that will permit the third party data evaluator to identify the locations to survey or certain metrics related to their services, including customer purchase options and service usage. This information might include customer contact information, when the recipient expects such locations might be offered service, and other specifics about the locations served. The Commission notes that when recipients submit data to the Commission or its designated third party data evaluator, they should ensure that their submission protects customer privacy consistent with applicable privacy laws and regulations.

F. Measures To Ensure Compliance

84. In the *Tech Transitions Order*, the Commission stated that support for the rural broadband experiments would be conditioned on "complying with all relevant universal service rules that the Commission has adopted or may adopt in the future in relevant rulemaking proceedings, including . . . enforcement mechanisms for non-compliance with rules." Here, the Commission adopts specific measures to ensure participants meet the terms and conditions of the rural broadband experiments.

85. The Commission has previously held that funds that are disbursed from the high-cost program in violation of a Commission rule that "implements the statute or a substantive program goal" should be recovered from the recipient. Thus, here the Commission adopts a process to recover support from recipients that do not comply with the terms and conditions of the rural broadband experiments after they begin receiving support. The Commission also notes that it intends to enforce the terms and conditions vigorously. Such measures uphold the integrity of the Fund by ensuring that recipients of high-cost support are using those funds for the purposes for which they are provided.

86. *Trigger for Performance Default.* A performance default will occur if the winning bidder begins receiving support and then fails to meet the terms and conditions of the rural broadband experiments. For example, if the winning bidder has failed to meet the build-out obligations adopted above, or the winning bidder failed to keep open and renew its LOC as required above, it will be a performance default. A performance default will also occur if the winning bidder does not offer service to the required number of locations that meet the public interest obligations the Commission has adopted for the experiments, including speed, latency, data usage, and reasonably comparable pricing. The Commission expects to verify that recipients of support are in fact meeting the terms and conditions of the rural broadband experiments by verifying the build-out evidence that they will submit with their annual reports and certifications.

87. For purposes of the rural broadband experiments, a Connect America recipient can demonstrate compliance with the speed, latency, data usage, and pricing requirements if it has met the build-out milestones by deploying robust networks that are capable of meeting the required public interest obligations, and its annual reports, certifications, and marketing materials demonstrate that the recipient is offering at least one package to the eligible locations at the required speeds, with a data usage allowance that meets the requirements for these experiments at reasonably comparable prices.

88. *Support Reductions and Recovery of Support.* If a recipient begins receiving support, and the Bureau subsequently determines that it fails to meet the terms and conditions of its experiment, the Bureau will issue a letter evidencing the default, and USAC will begin withholding support. For the first six months that the entity is not in

compliance, USAC will withhold five percent of the entity's total monthly support. For the next six months that the entity is not in compliance, USAC will withhold 25 percent of the entity's total monthly support. If at any point during the year that the support is being withheld the winning bidder comes into compliance, the Bureau will issue a letter to that effect; the entity then will be entitled to have its full support restored and will be able to recover all the support that USAC withheld.

89. If at the end of this year period, the entity is still not in compliance, the Bureau will issue a letter to that effect, and USAC will draw on the entity's LOC for the recovery of all support that has been authorized. If after USAC recovers the support under the LOC, the winning bidder is able to demonstrate that it has come into compliance with the experiment's terms and conditions at any time before the support period ends, it will be entitled to have its past support restored and will be eligible for any remaining disbursements of authorized support. But if the winning bidder is unable to demonstrate compliance at any point during the support term after its support has been recovered by the Bureau, the entity will not be eligible to have any of its recovered support restored or to receive any remaining disbursements. An entity may only exercise this cure opportunity once. The recovered support, along with the remaining authorized support that has not yet been disbursed, will not be authorized for another experiment.

90. *Forfeiture.* To further impress upon recipients the importance of complying with the rural broadband experiments' terms and conditions, the Commission notes that it will enforce these requirements vigorously. The Enforcement Bureau may initiate an enforcement proceeding in the event of a default or after the Bureau issues a letter evidencing the recipient's default. In proposing any forfeiture, consistent with the Commission's rules, the Enforcement Bureau shall take into account the nature, circumstances, extent, and gravity of the violations.

91. *Waiver.* In the event a recipient is unable to meet the terms and conditions of the rural broadband experiments due to circumstances beyond its control (e.g., a severe weather event), that entity may petition for a waiver of the relevant terms and conditions prior to the relevant build-out milestone pursuant to § 1.3 of the Commission's rules. The petitioning entity will then have the cure period described above to meet the terms and conditions of the experiment. The Commission encourages entities that submit petitions for waiver to

continue to work diligently towards meeting the terms and conditions of their experiments while their petitions are pending. If the petitioning entity is unable to meet the terms and conditions during the relevant cure period, and no decision has been issued on the waiver petition, the Bureau will issue a letter finding default, USAC will draw on the LOC, and the Enforcement Bureau may initiate forfeiture proceedings. If the waiver subsequently is granted, the petitioning entity will have all of the funds that have been recovered restored and will be entitled to receive its subsequent disbursements. The Commission notes that a winning bidder's inability to secure the proper permits and other permissions to build its network would not constitute grounds for waiver and will be considered a default if the winning bidder is unable to meet its build-out and public interest obligations due to its inability to secure such permits. The Commission expects that entities choosing to participate in the rural broadband experiments will do their due diligence and determine which permits and other permissions will be required and what steps they will need to take to obtain such permissions before submitting their applications.

92. *Other Consequences for Non-Compliance.* Recipients of funding in the rural broadband experiments will be subject to the Commission's rules related to reductions in support in the event that they fail to meet reporting and certification deadlines. Recipients may also be subject other sanctions for non-compliance with the terms and conditions of the rural broadband experiments or the Commission's rules, including, but not limited to, potential revocation of ETC designation and disqualification from future competitive bidding for universal service support.

III. Procedural Matters

A. Paperwork Reduction Analysis

93. The Report and Order contains new and modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA). It will be submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the PRA. OMB, the general public, and other Federal agencies are invited to comment on the new or modified information collection requirements contained in this proceeding. In addition, the Commission notes that pursuant to the Small Business Paperwork Relief Act of 2002, it previously sought specific comment on how the Commission might further

reduce the information collection burden for small business concerns with fewer than 25 employees. The Commission describes impacts that might affect small businesses, which includes most businesses with fewer than 25 employees, in the Final Regulatory Flexibility Analysis (FRFA) in Appendix B, *infra*.

B. Final Regulatory Flexibility Analysis

94. As required by the Regulatory Flexibility Act of 1980 (RFA), as amended, an Initial Regulatory Flexibility Analyses (IRFA) was incorporated in the *Further Notice of Proposed Rulemaking (USF/ICC Transformation FNPRM)*. The Commission sought written public comment on the proposals in the *USF/ICC Transformation FNPRM*, including comment on the IRFA. The Commission also invited parties to file comments on this IRFA in the *Tech Transitions FNPRM*. The Commission did not receive any relevant comments on the *USF/ICC Transformation FNPRM* IRFA. This Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.

A. Need for, and Objectives of the Report and Order

95. The Commission explained in the *Tech Transitions Order* that the Commission must "ensure that all Americans benefit from the technology transitions, and that it gains data on the impact of technology transitions in rural areas, including Tribal lands, where residential consumers, small businesses and anchor institutions, including schools, libraries and health care providers, may not have access to advanced broadband services." In this Order, the Commission adopts certain parameters and requirements for the rural broadband experiments that will assist us with accomplishing these goals. The Commission expects these experiments to provide critical information regarding which and what types of parties are willing to build networks that will deliver services that exceed our current performance standards for an amount of money equal to or less than the support amounts calculated by the adopted Phase II Connect America Cost Model. In addition to gathering information relevant to broader questions implicated by technology transitions, the Commission expects these experiments also will inform key decisions that the Commission will be making in the coming months regarding the Connect America Fund.

96. The Commission adopts a budget of \$100 million for funding experiments in price cap areas focused on bringing

robust, scalable broadband networks to residential and small business locations in rural communities that are not served by an unsubsidized competitor that offers voice and Internet access delivering at least 3 Mbps downstream/768 kbps upstream. The funding will be available to serve locations in both high-cost and extremely high-cost areas, thereby advancing our implementation of both Phase II and the Remote Areas Fund. Applications will be due 90 days from the release of this Order. The Commission also determines the objective methodology for selecting projects among the applications it receives for the experiments. Given the manner in which the Commission has structured the budget and the selection criteria, it believes that it will be able to fund a range of diverse projects throughout the country. Finally, the Commission outlines the conditions that entities participating in the experiments must meet in order to continue to receive such support, including specific eligibility, build-out and accountability requirements, and establish the measures to ensure compliance with these conditions.

B. Summary of Significant Issues Raised by Public Comments in Response to the IRFA

97. There were no relevant comments filed that specifically addressed the rules and policies proposed in the *USF/ICC Transformation FNPRM IRFA*.

C. Description and Estimate of the Number of Small Entities to Which the Rules Will Apply

98. The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the rules adopted herein. The RFA generally defines the term “small entity” as having the same meaning as the terms “small business,” “small organization,” and “small governmental jurisdiction.” In addition, the term “small business” has the same meaning as the term “small-business concern” under the Small Business Act. A “small-business concern” is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

99. *Small Businesses.* Nationwide, there are a total of approximately 28.2 million small businesses, according to the SBA.

100. *Wired Telecommunications Carriers.* The SBA has developed a small business size standard for Wired Telecommunications Carriers, which consists of all such companies having

1,500 or fewer employees. According to Census Bureau data for 2007, there were 3,188 firms in this category, total, that operated for the entire year. Of this total, 3144 firms had employment of 999 or fewer employees, and 44 firms had employment of 1000 employees or more. Thus, under this size standard, the majority of firms can be considered small.

101. *Local Exchange Carriers (LECs).* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to local exchange services. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 1,307 carriers reported that they were incumbent local exchange service providers. Of these 1,307 carriers, an estimated 1,006 have 1,500 or fewer employees and 301 have more than 1,500 employees. Consequently, the Commission estimates that most providers of local exchange service are small entities that may be affected by the rules and policies proposed in the Order.

102. *Incumbent Local Exchange Carriers (incumbent LECs).* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to incumbent local exchange services. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 1,307 carriers reported that they were incumbent local exchange service providers. Of these 1,307 carriers, an estimated 1,006 have 1,500 or fewer employees and 301 have more than 1,500 employees. Consequently, the Commission estimates that most providers of incumbent local exchange service are small businesses that may be affected by rules adopted pursuant to the Order.

103. The Commission has included small incumbent LECs in this present RFA analysis. As noted above, a “small business” under the RFA is one that, *inter alia*, meets the pertinent small business size standard (e.g., a telephone communications business having 1,500 or fewer employees), and “is not dominant in its field of operation.” The SBA’s Office of Advocacy contends that, for RFA purposes, small incumbent LECs are not dominant in their field of operation because any such dominance is not “national” in scope. The Commission has therefore included small incumbent LECs in this RFA

analysis, although it emphasizes that this RFA action has no effect on Commission analyses and determinations in other, non-RFA contexts.

104. *Competitive Local Exchange Carriers (competitive LECs), Competitive Access Providers (CAPs), Shared-Tenant Service Providers, and Other Local Service Providers.* Neither the Commission nor the SBA has developed a small business size standard specifically for these service providers. The appropriate size standard under SBA rules is for the category Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 1,442 carriers reported that they were engaged in the provision of either competitive local exchange services or competitive access provider services. Of these 1,442 carriers, an estimated 1,256 have 1,500 or fewer employees and 186 have more than 1,500 employees. In addition, 17 carriers have reported that they are Shared-Tenant Service Providers, and all 17 are estimated to have 1,500 or fewer employees. In addition, 72 carriers have reported that they are Other Local Service Providers. Of the 72, seventy have 1,500 or fewer employees and two have more than 1,500 employees. Consequently, the Commission estimates that most providers of competitive local exchange service, competitive access providers, Shared-Tenant Service Providers, and Other Local Service Providers are small entities that may be affected by rules adopted pursuant to the Order.

105. *Interexchange Carriers (IXCs).* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to interexchange services. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 359 companies reported that their primary telecommunications service activity was the provision of interexchange services. Of these 359 companies, an estimated 317 have 1,500 or fewer employees and 42 have more than 1,500 employees. Consequently, the Commission estimates that the majority of interexchange service providers are small entities that may be affected by rules adopted pursuant to the Order.

106. *Prepaid Calling Card Providers.* Neither the Commission nor the SBA has developed a small business size standard specifically for prepaid calling card providers. The appropriate size

standard under SBA rules is for the category Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 193 carriers have reported that they are engaged in the provision of prepaid calling cards. Of these, an estimated all 193 have 1,500 or fewer employees and none have more than 1,500 employees. Consequently, the Commission estimates that the majority of prepaid calling card providers are small entities that may be affected by rules adopted pursuant to the Order.

107. *Local Resellers.* The SBA has developed a small business size standard for the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 213 carriers have reported that they are engaged in the provision of local resale services. Of these, an estimated 211 have 1,500 or fewer employees and two have more than 1,500 employees. Consequently, the Commission estimates that the majority of local resellers are small entities that may be affected by rules adopted pursuant to the Order.

108. *Toll Resellers.* The SBA has developed a small business size standard for the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 881 carriers have reported that they are engaged in the provision of toll resale services. Of these, an estimated 857 have 1,500 or fewer employees and 24 have more than 1,500 employees. Consequently, the Commission estimates that the majority of toll resellers are small entities that may be affected by rules adopted pursuant to the Order.

109. *Other Toll Carriers.* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to Other Toll Carriers. This category includes toll carriers that do not fall within the categories of interexchange carriers, operator service providers, prepaid calling card providers, satellite service carriers, or toll resellers. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 284 companies reported that their primary telecommunications service activity was the provision of other toll carriage. Of these, an estimated 279 have 1,500 or

fewer employees and five have more than 1,500 employees. Consequently, the Commission estimates that most Other Toll Carriers are small entities that may be affected by the rules and policies adopted pursuant to the Order.

110. *800 and 800-Like Service Subscribers.* Neither the Commission nor the SBA has developed a small business size standard specifically for 800 and 800-like service (toll free) subscribers. The appropriate size standard under SBA rules is for the category Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. The most reliable source of information regarding the number of these service subscribers appears to be data the Commission collects on the 800, 888, 877, and 866 numbers in use. According to our data, as of September 2009, the number of 800 numbers assigned was 7,860,000; the number of 888 numbers assigned was 5,588,687; the number of 877 numbers assigned was 4,721,866; and the number of 866 numbers assigned was 7,867,736. The Commission does not have data specifying the number of these subscribers that are not independently owned and operated or have more than 1,500 employees, and thus are unable at this time to estimate with greater precision the number of toll free subscribers that would qualify as small businesses under the SBA size standard. Consequently, the Commission estimates that there are 7,860,000 or fewer small entity 800 subscribers; 5,588,687 or fewer small entity 888 subscribers; 4,721,866 or fewer small entity 877 subscribers; and 7,867,736 or fewer small entity 866 subscribers.

111. *Wireless Telecommunications Carriers (except Satellite).* Since 2007, the SBA has recognized wireless firms within this new, broad, economic census category. Prior to that time, such firms were within the now-superseded categories of Paging and Cellular and Other Wireless Telecommunications. Under the present and prior categories, the SBA has deemed a wireless business to be small if it has 1,500 or fewer employees. For this category, census data for 2007 show that there were 1,383 firms that operated for the entire year. Of this total, 1,368 firms had employment of 999 or fewer employees and 15 had employment of 1000 employees or more. Similarly, according to Commission data, 413 carriers reported that they were engaged in the provision of wireless telephony, including cellular service, Personal Communications Service (PCS), and Specialized Mobile Radio (SMR) Telephony services. Of these, an

estimated 261 have 1,500 or fewer employees and 152 have more than 1,500 employees. Consequently, the Commission estimates that approximately half or more of these firms can be considered small. Thus, using available data, the Commission estimates that the majority of wireless firms can be considered small.

112. *Broadband Personal Communications Service.* The broadband personal communications service (PCS) spectrum is divided into six frequency blocks designated A through F, and the Commission has held auctions for each block. The Commission defined “small entity” for Blocks C and F as an entity that has average gross revenues of \$40 million or less in the three previous calendar years. For Block F, an additional classification for “very small business” was added and is defined as an entity that, together with its affiliates, has average gross revenues of not more than \$15 million for the preceding three calendar years. These standards defining “small entity” in the context of broadband PCS auctions have been approved by the SBA. No small businesses, within the SBA-approved small business size standards bid successfully for licenses in Blocks A and B. There were 90 winning bidders that qualified as small entities in the Block C auctions. A total of 93 small and very small business bidders won approximately 40 percent of the 1,479 licenses for Blocks D, E, and F. In 1999, the Commission re-auctioned 347 C, E, and F Block licenses. There were 48 small business winning bidders. In 2001, the Commission completed the auction of 422 C and F Broadband PCS licenses in Auction 35. Of the 35 winning bidders in this auction, 29 qualified as “small” or “very small” businesses. Subsequent events, concerning Auction 35, including judicial and agency determinations, resulted in a total of 163 C and F Block licenses being available for grant. In 2005, the Commission completed an auction of 188 C block licenses and 21 F block licenses in Auction 58. There were 24 winning bidders for 217 licenses. Of the 24 winning bidders, 16 claimed small business status and won 156 licenses. In 2007, the Commission completed an auction of 33 licenses in the A, C, and F Blocks in Auction 71. Of the 14 winning bidders, six were designated entities. In 2008, the Commission completed an auction of 20 Broadband PCS licenses in the C, D, E and F block licenses in Auction 78.

113. *Advanced Wireless Services.* In 2008, the Commission conducted the auction of Advanced Wireless Services

("AWS") licenses. This auction, which as designated as Auction 78, offered 35 licenses in the AWS 1710–1755 MHz and 2110–2155 MHz bands (AWS–1). The AWS–1 licenses were licenses for which there were no winning bids in Auction 66. That same year, the Commission completed Auction 78. A bidder with attributed average annual gross revenues that exceeded \$15 million and did not exceed \$40 million for the preceding three years ("small business") received a 15 percent discount on its winning bid. A bidder with attributed average annual gross revenues that did not exceed \$15 million for the preceding three years ("very small business") received a 25 percent discount on its winning bid. A bidder that had combined total assets of less than \$500 million and combined gross revenues of less than \$125 million in each of the last two years qualified for entrepreneur status. Four winning bidders that identified themselves as very small businesses won 17 licenses. Three of the winning bidders that identified themselves as a small business won five licenses. Additionally, one other winning bidder that qualified for entrepreneur status won 2 licenses.

114. *Narrowband Personal Communications Services*. In 1994, the Commission conducted an auction for Narrowband PCS licenses. A second auction was also conducted later in 1994. For purposes of the first two Narrowband PCS auctions, "small businesses" were entities with average gross revenues for the prior three calendar years of \$40 million or less. Through these auctions, the Commission awarded a total of 41 licenses, 11 of which were obtained by four small businesses. To ensure meaningful participation by small business entities in future auctions, the Commission adopted a two-tiered small business size standard in the *Narrowband PCS Second Report and Order*, 65 FR 35843, June 6, 2000. A "small business" is an entity that, together with affiliates and controlling interests, has average gross revenues for the three preceding years of not more than \$40 million. A "very small business" is an entity that, together with affiliates and controlling interests, has average gross revenues for the three preceding years of not more than \$15 million. The SBA has approved these small business size standards. A third auction was conducted in 2001. Here, five bidders won 317 (Metropolitan Trading Areas and nationwide) licenses. Three of these claimed status as a small

or very small entity and won 311 licenses.

115. *Paging (Private and Common Carrier)*. In the *Paging Third Report and Order*, 64 FR 33762, June 24, 1999, the Commission developed a small business size standard for "small businesses" and "very small businesses" for purposes of determining their eligibility for special provisions such as bidding credits and installment payments. A "small business" is an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding \$15 million for the preceding three years. Additionally, a "very small business" is an entity that, together with its affiliates and controlling principals, has average gross revenues that are not more than \$3 million for the preceding three years. The SBA has approved these small business size standards. According to Commission data, 291 carriers have reported that they are engaged in Paging or Messaging Service. Of these, an estimated 289 have 1,500 or fewer employees, and two have more than 1,500 employees. Consequently, the Commission estimates that the majority of paging providers are small entities that may be affected by our action. An auction of Metropolitan Economic Area licenses commenced on February 24, 2000, and closed on March 2, 2000. Of the 2,499 licenses auctioned, 985 were sold. Fifty-seven companies claiming small business status won 440 licenses. A subsequent auction of MEA and Economic Area ("EA") licenses was held in the year 2001. Of the 15,514 licenses auctioned, 5,323 were sold. One hundred thirty-two companies claiming small business status purchased 3,724 licenses. A third auction, consisting of 8,874 licenses in each of 175 EAs and 1,328 licenses in all but three of the 51 MEAs, was held in 2003. Seventy-seven bidders claiming small or very small business status won 2,093 licenses. A fourth auction, consisting of 9,603 lower and upper paging band licenses was held in the year 2010. Twenty-nine bidders claiming small or very small business status won 3,016 licenses.

116. *220 MHz Radio Service—Phase I Licensees*. The 220 MHz service has both Phase I and Phase II licenses. Phase I licensing was conducted by lotteries in 1992 and 1993. There are approximately 1,515 such non-nationwide licensees and four nationwide licensees currently authorized to operate in the 220 MHz band. The Commission has not developed a small business size standard for small entities specifically applicable to such incumbent 220 MHz Phase I licensees. To estimate the number of such licensees that are small

businesses, the Commission applies the small business size standard under the SBA rules applicable to Wireless Telecommunications Carriers (except Satellite). Under this category, the SBA deems a wireless business to be small if it has 1,500 or fewer employees. The Commission estimates that nearly all such licensees are small businesses under the SBA's small business size standard that may be affected by rules adopted pursuant to the Order.

117. *220 MHz Radio Service—Phase II Licensees*. The 220 MHz service has both Phase I and Phase II licenses. The Phase II 220 MHz service is subject to spectrum auctions. In the *220 MHz Third Report and Order*, 62 FR 15978, April 3, 1997, the Commission adopted a small business size standard for "small" and "very small" businesses for purposes of determining their eligibility for special provisions such as bidding credits and installment payments. This small business size standard indicates that a "small business" is an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding \$15 million for the preceding three years. A "very small business" is an entity that, together with its affiliates and controlling principals, has average gross revenues that do not exceed \$3 million for the preceding three years. The SBA has approved these small business size standards. Auctions of Phase II licenses commenced on September 15, 1998, and closed on October 22, 1998. In the first auction, 908 licenses were auctioned in three different-sized geographic areas: three nationwide licenses, 30 Regional Economic Area Group (EAG) Licenses, and 875 Economic Area (EA) Licenses. Of the 908 licenses auctioned, 693 were sold. Thirty-nine small businesses won licenses in the first 220 MHz auction. The second auction included 225 licenses: 216 EA licenses and 9 EAG licenses. Fourteen companies claiming small business status won 158 licenses.

118. *Specialized Mobile Radio*. The Commission awards small business bidding credits in auctions for Specialized Mobile Radio ("SMR") geographic area licenses in the 800 MHz and 900 MHz bands to entities that had revenues of no more than \$15 million in each of the three previous calendar years. The Commission awards very small business bidding credits to entities that had revenues of no more than \$3 million in each of the three previous calendar years. The SBA has approved these small business size standards for the 800 MHz and 900 MHz SMR Services. The Commission has held auctions for geographic area licenses in the 800 MHz and 900 MHz

bands. The 900 MHz SMR auction was completed in 1996. Sixty bidders claiming that they qualified as small businesses under the \$15 million size standard won 263 geographic area licenses in the 900 MHz SMR band. The 800 MHz SMR auction for the upper 200 channels was conducted in 1997. Ten bidders claiming that they qualified as small businesses under the \$15 million size standard won 38 geographic area licenses for the upper 200 channels in the 800 MHz SMR band. A second auction for the 800 MHz band was conducted in 2002 and included 23 BEA licenses. One bidder claiming small business status won five licenses.

119. The auction of the 1,053 800 MHz SMR geographic area licenses for the General Category channels was conducted in 2000. Eleven bidders won 108 geographic area licenses for the General Category channels in the 800 MHz SMR band qualified as small businesses under the \$15 million size standard. In an auction completed in 2000, a total of 2,800 Economic Area licenses in the lower 80 channels of the 800 MHz SMR service were awarded. Of the 22 winning bidders, 19 claimed small business status and won 129 licenses. Thus, combining all three auctions, 40 winning bidders for geographic licenses in the 800 MHz SMR band claimed status as small business.

120. In addition, there are numerous incumbent site-by-site SMR licensees and licensees with extended implementation authorizations in the 800 and 900 MHz bands. The Commission does not know how many firms provide 800 MHz or 900 MHz geographic area SMR pursuant to extended implementation authorizations, nor how many of these providers have annual revenues of no more than \$15 million. One firm has over \$15 million in revenues. In addition, the Commission does not know how many of these firms have 1,500 or fewer employees. The Commission assumes, for purposes of this analysis, that all of the remaining existing extended implementation authorizations are held by small entities, as that small business size standard is approved by the SBA.

121. *Broadband Radio Service and Educational Broadband Service.* Broadband Radio Service systems, previously referred to as Multipoint Distribution Service (“MDS”) and Multichannel Multipoint Distribution Service (“MMDS”) systems, and “wireless cable,” transmit video programming to subscribers and provide two-way high speed data operations using the microwave frequencies of the

Broadband Radio Service (“BRS”) and Educational Broadband Service (“EBS”) (previously referred to as the Instructional Television Fixed Service (“ITFS”). In connection with the 1996 BRS auction, the Commission established a small business size standard as an entity that had annual average gross revenues of no more than \$40 million in the previous three calendar years. The BRS auctions resulted in 67 successful bidders obtaining licensing opportunities for 493 Basic Trading Areas (“BTAs”). Of the 67 auction winners, 61 met the definition of a small business. BRS also includes licensees of stations authorized prior to the auction. At this time, the Commission estimates that of the 61 small business BRS auction winners, 48 remain small business licensees. In addition to the 48 small businesses that hold BTA authorizations, there are approximately 392 incumbent BRS licensees that are considered small entities. After adding the number of small business auction licensees to the number of incumbent licensees not already counted, the Commission finds that there are currently approximately 440 BRS licensees that are defined as small businesses under either the SBA or the Commission’s rules. The Commission has adopted three levels of bidding credits for BRS: (i) A bidder with attributed average annual gross revenues that exceed \$15 million and do not exceed \$40 million for the preceding three years (small business) is eligible to receive a 15 percent discount on its winning bid; (ii) a bidder with attributed average annual gross revenues that exceed \$3 million and do not exceed \$15 million for the preceding three years (very small business) is eligible to receive a 25 percent discount on its winning bid; and (iii) a bidder with attributed average annual gross revenues that do not exceed \$3 million for the preceding three years (entrepreneur) is eligible to receive a 35 percent discount on its winning bid. In 2009, the Commission conducted Auction 86, which offered 78 BRS licenses. Auction 86 concluded with ten bidders winning 61 licenses. Of the ten, two bidders claimed small business status and won 4 licenses; one bidder claimed very small business status and won three licenses; and two bidders claimed entrepreneur status and won six licenses.

122. In addition, the SBA’s Cable Television Distribution Services small business size standard is applicable to EBS. There are presently 2,032 EBS licensees. All but 100 of these licenses are held by educational institutions.

Educational institutions are included in this analysis as small entities. Thus, the Commission estimates that at least 1,932 licensees are small businesses. Since 2007, Cable Television Distribution Services have been defined within the broad economic census category of Wired Telecommunications Carriers; that category is defined as follows: “This industry comprises establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or a combination of technologies.” The SBA defines a small business size standard for this category as any such firms having 1,500 or fewer employees. The SBA has developed a small business size standard for this category, which is: all such firms having 1,500 or fewer employees. According to Census Bureau data for 2007, there were a total of 955 firms in this previous category that operated for the entire year. Of this total, 939 firms had employment of 999 or fewer employees, and 16 firms had employment of 1000 employees or more. Thus, under this size standard, the majority of firms can be considered small and may be affected by rules adopted pursuant to the Order.

123. *Lower 700 MHz Band Licenses.* The Commission previously adopted criteria for defining three groups of small businesses for purposes of determining their eligibility for special provisions such as bidding credits. The Commission defined a “small business” as an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding \$40 million for the preceding three years. A “very small business” is defined as an entity that, together with its affiliates and controlling principals, has average gross revenues that are not more than \$15 million for the preceding three years. Additionally, the Lower 700 MHz Band had a third category of small business status for Metropolitan/Rural Service Area (“MSA/RSA”) licenses, identified as “entrepreneur” and defined as an entity that, together with its affiliates and controlling principals, has average gross revenues that are not more than \$3 million for the preceding three years. The SBA approved these small size standards. The Commission conducted an auction in 2002 of 740 Lower 700 MHz Band licenses (one license in each of the 734 MSAs/RSAs and one license in each of the six Economic Area Groupings (EAGs)). Of

the 740 licenses available for auction, 484 licenses were sold to 102 winning bidders. Seventy-two of the winning bidders claimed small business, very small business or entrepreneur status and won a total of 329 licenses. The Commission conducted a second Lower 700 MHz Band auction in 2003 that included 256 licenses: 5 EAG licenses and 476 Cellular Market Area licenses. Seventeen winning bidders claimed small or very small business status and won 60 licenses, and nine winning bidders claimed entrepreneur status and won 154 licenses. In 2005, the Commission completed an auction of 5 licenses in the Lower 700 MHz Band, designated Auction 60. There were three winning bidders for five licenses. All three winning bidders claimed small business status.

124. In 2007, the Commission reexamined its rules governing the 700 MHz band in the *700 MHz Second Report and Order*, 72 FR 48814, August 24, 2007. The *700 MHz Second Report and Order* revised the band plan for the commercial (including Guard Band) and public safety spectrum, adopted services rules, including stringent build-out requirements, an open platform requirement on the C Block, and a requirement on the D Block licensee to construct and operate a nationwide, interoperable wireless broadband network for public safety users. An auction of A, B and E block licenses in the Lower 700 MHz band was held in 2008. Twenty winning bidders claimed small business status (those with attributable average annual gross revenues that exceed \$15 million and do not exceed \$40 million for the preceding three years). Thirty three winning bidders claimed very small business status (those with attributable average annual gross revenues that do not exceed \$15 million for the preceding three years). In 2011, the Commission conducted Auction 92, which offered 16 Lower 700 MHz band licenses that had been made available in Auction 73 but either remained unsold or were licenses on which a winning bidder defaulted. Two of the seven winning bidders in Auction 92 claimed very small business status, winning a total of four licenses.

125. *Upper 700 MHz Band Licenses*. In the *700 MHz Second Report and Order*, the Commission revised its rules regarding Upper 700 MHz band licenses. In 2008, the Commission conducted Auction 73 in which C and D block licenses in the Upper 700 MHz band were available. Three winning bidders claimed very small business status (those with attributable average annual gross revenues that do not

exceed \$15 million for the preceding three years).

126. *700 MHz Guard Band Licensees*. In the *700 MHz Guard Band Order*, 65 FR 17594, April 4, 2000, the Commission adopted a small business size standard for “small businesses” and “very small businesses” for purposes of determining their eligibility for special provisions such as bidding credits and installment payments. A “small business” is an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding \$40 million for the preceding three years. Additionally, a “very small business” is an entity that, together with its affiliates and controlling principals, has average gross revenues that are not more than \$15 million for the preceding three years. An auction of 52 Major Economic Area (MEA) licenses commenced on September 6, 2000, and closed on September 21, 2000. Of the 104 licenses auctioned, 96 licenses were sold to nine bidders. Five of these bidders were small businesses that won a total of 26 licenses. A second auction of 700 MHz Guard Band licenses commenced on February 13, 2001 and closed on February 21, 2001. All eight of the licenses auctioned were sold to three bidders. One of these bidders was a small business that won a total of two licenses.

127. *Cellular Radiotelephone Service*. Auction 77 was held to resolve one group of mutually exclusive applications for Cellular Radiotelephone Service licenses for unserved areas in New Mexico. Bidding credits for designated entities were not available in Auction 77. In 2008, the Commission completed the closed auction of one unserved service area in the Cellular Radiotelephone Service, designated as Auction 77. Auction 77 concluded with one provisionally winning bid for the unserved area totaling \$25,002.

128. *Private Land Mobile Radio (“PLMR”)*. PLMR systems serve an essential role in a range of industrial, business, land transportation, and public safety activities. These radios are used by companies of all sizes operating in all U.S. business categories, and are often used in support of the licensee’s primary (non-telecommunications) business operations. For the purpose of determining whether a licensee of a PLMR system is a small business as defined by the SBA, the Commission uses the broad census category, Wireless Telecommunications Carriers (except Satellite). This definition provides that a small entity is any such entity employing no more than 1,500 persons. The Commission does not require PLMR licensees to disclose information about

number of employees, so the Commission does not have information that could be used to determine how many PLMR licensees constitute small entities under this definition. The Commission notes that PLMR licensees generally use the licensed facilities in support of other business activities, and therefore, it would also be helpful to assess PLMR licensees under the standards applied to the particular industry subsector to which the licensee belongs.

129. As of March 2010, there were 424,162 PLMR licensees operating 921,909 transmitters in the PLMR bands below 512 MHz. The Commission notes that any entity engaged in a commercial activity is eligible to hold a PLMR license, and that any revised rules in this context could therefore potentially impact small entities covering a great variety of industries.

130. *Rural Radiotelephone Service*. The Commission has not adopted a size standard for small businesses specific to the Rural Radiotelephone Service. A significant subset of the Rural Radiotelephone Service is the Basic Exchange Telephone Radio System (BETRS). In the present context, the Commission will use the SBA’s small business size standard applicable to Wireless Telecommunications Carriers (except Satellite), i.e., an entity employing no more than 1,500 persons. There are approximately 1,000 licensees in the Rural Radiotelephone Service, and the Commission estimates that there are 1,000 or fewer small entity licensees in the Rural Radiotelephone Service that may be affected by the rules and policies proposed herein.

131. *Air-Ground Radiotelephone Service*. The Commission has not adopted a small business size standard specific to the Air-Ground Radiotelephone Service. The Commission will use SBA’s small business size standard applicable to Wireless Telecommunications Carriers (except Satellite), i.e., an entity employing no more than 1,500 persons. There are approximately 100 licensees in the Air-Ground Radiotelephone Service, and the Commission estimates that almost all of them qualify as small under the SBA small business size standard and may be affected by rules adopted pursuant to the Order.

132. *Aviation and Marine Radio Services*. Small businesses in the aviation and marine radio services use a very high frequency (VHF) marine or aircraft radio and, as appropriate, an emergency position-indicating radio beacon (and/or radar) or an emergency locator transmitter. The Commission has not developed a small business size

standard specifically applicable to these small businesses. For purposes of this analysis, the Commission uses the SBA small business size standard for the category Wireless Telecommunications Carriers (except Satellite), which is 1,500 or fewer employees. Census data for 2007, which supersede data contained in the 2002 Census, show that there were 1,383 firms that operated that year. Of those 1,383, 1,368 had fewer than 100 employees, and 15 firms had more than 100 employees. Most applicants for recreational licenses are individuals. Approximately 581,000 ship station licensees and 131,000 aircraft station licensees operate domestically and are not subject to the radio carriage requirements of any statute or treaty. For purposes of our evaluations in this analysis, the Commission estimates that there are up to approximately 712,000 licensees that are small businesses (or individuals) under the SBA standard. In addition, between December 3, 1998 and December 14, 1998, the Commission held an auction of 42 VHF Public Coast licenses in the 157.1875–157.4500 MHz (ship transmit) and 161.775–162.0125 MHz (coast transmit) bands. For purposes of the auction, the Commission defined a “small” business as an entity that, together with controlling interests and affiliates, has average gross revenues for the preceding three years not to exceed \$15 million dollars. In addition, a “very small” business is one that, together with controlling interests and affiliates, has average gross revenues for the preceding three years not to exceed \$3 million dollars. There are approximately 10,672 licensees in the Marine Coast Service, and the Commission estimates that almost all of them qualify as “small” businesses under the above special small business size standards and may be affected by rules adopted pursuant to the Order.

133. *Fixed Microwave Services.* Fixed microwave services include common carrier, private operational-fixed, and broadcast auxiliary radio services. At present, there are approximately 22,015 common carrier fixed licensees and 61,670 private operational-fixed licensees and broadcast auxiliary radio licensees in the microwave services. The Commission has not created a size standard for a small business specifically with respect to fixed microwave services. For purposes of this analysis, the Commission uses the SBA small business size standard for Wireless Telecommunications Carriers (except Satellite), which is 1,500 or fewer employees. The Commission does

not have data specifying the number of these licensees that have more than 1,500 employees, and thus is unable at this time to estimate with greater precision the number of fixed microwave service licensees that would qualify as small business concerns under the SBA’s small business size standard. Consequently, the Commission estimates that there are up to 22,015 common carrier fixed licensees and up to 61,670 private operational-fixed licensees and broadcast auxiliary radio licensees in the microwave services that may be small and may be affected by the rules and policies adopted herein. The Commission notes, however, that the common carrier microwave fixed licensee category includes some large entities.

134. *Offshore Radiotelephone Service.* This service operates on several UHF television broadcast channels that are not used for television broadcasting in the coastal areas of states bordering the Gulf of Mexico. There are presently approximately 55 licensees in this service. The Commission is unable to estimate at this time the number of licensees that would qualify as small under the SBA’s small business size standard for the category of Wireless Telecommunications Carriers (except Satellite). Under that SBA small business size standard, a business is small if it has 1,500 or fewer employees. Census data for 2007, which supersede data contained in the 2002 Census, show that there were 1,383 firms that operated that year. Of those 1,383, 1,368 had fewer than 100 employees, and 15 firms had more than 100 employees. Thus, under this category and the associated small business size standard, the majority of firms can be considered small.

135. *39 GHz Service.* The Commission created a special small business size standard for 39 GHz licenses—an entity that has average gross revenues of \$40 million or less in the three previous calendar years. An additional size standard for “very small business” is: an entity that, together with affiliates, has average gross revenues of not more than \$15 million for the preceding three calendar years. The SBA has approved these small business size standards. The auction of the 2,173 39 GHz licenses began on April 12, 2000 and closed on May 8, 2000. The 18 bidders who claimed small business status won 849 licenses. Consequently, the Commission estimates that 18 or fewer 39 GHz licensees are small entities that may be affected by rules adopted pursuant to the Order.

136. *Local Multipoint Distribution Service.* Local Multipoint Distribution Service (LMDS) is a fixed broadband point-to-multipoint microwave service that provides for two-way video telecommunications. The auction of the 986 LMDS licenses began and closed in 1998. The Commission established a small business size standard for LMDS licensees as an entity that has average gross revenues of less than \$40 million in the three previous calendar years. An additional small business size standard for “very small business” was added as an entity that, together with its affiliates, has average gross revenues of not more than \$15 million for the preceding three calendar years. The SBA has approved these small business size standards in the context of LMDS auctions. There were 93 winning bidders that qualified as small entities in the LMDS auctions. A total of 93 small and very small business bidders won approximately 277 A Block licenses and 387 B Block licenses. In 1999, the Commission re-auctioned 161 licenses; there were 32 small and very small businesses winning that won 119 licenses.

137. *218–219 MHz Service.* The first auction of 218–219 MHz spectrum resulted in 170 entities winning licenses for 594 Metropolitan Statistical Area (MSA) licenses. Of the 594 licenses, 557 were won by entities qualifying as a small business. For that auction, the small business size standard was an entity that, together with its affiliates, has no more than a \$6 million net worth and, after federal income taxes (excluding any carry over losses), has no more than \$2 million in annual profits each year for the previous two years. In the *218–219 MHz Report and Order and Memorandum Opinion and Order*, 64 FR 59656, November 3, 1999, the Commission established a small business size standard for a “small business” as an entity that, together with its affiliates and persons or entities that hold interests in such an entity and their affiliates, has average annual gross revenues not to exceed \$15 million for the preceding three years. A “very small business” is defined as an entity that, together with its affiliates and persons or entities that hold interests in such an entity and its affiliates, has average annual gross revenues not to exceed \$3 million for the preceding three years. These size standards will be used in future auctions of 218–219 MHz spectrum.

138. *2.3 GHz Wireless Communications Services.* This service can be used for fixed, mobile, radiolocation, and digital audio broadcasting satellite uses. The Commission defined “small business”

for the wireless communications services (“WCS”) auction as an entity with average gross revenues of \$40 million for each of the three preceding years, and a “very small business” as an entity with average gross revenues of \$15 million for each of the three preceding years. The SBA has approved these definitions. The Commission auctioned geographic area licenses in the WCS service. In the auction, which was conducted in 1997, there were seven bidders that won 31 licenses that qualified as very small business entities, and one bidder that won one license that qualified as a small business entity.

139. *1670–1675 MHz Band.* An auction for one license in the 1670–1675 MHz band was conducted in 2003. The Commission defined a “small business” as an entity with attributable average annual gross revenues of not more than \$40 million for the preceding three years and thus would be eligible for a 15 percent discount on its winning bid for the 1670–1675 MHz band license. Further, the Commission defined a “very small business” as an entity with attributable average annual gross revenues of not more than \$15 million for the preceding three years and thus would be eligible to receive a 25 percent discount on its winning bid for the 1670–1675 MHz band license. One license was awarded. The winning bidder was not a small entity.

140. *3650–3700 MHz band.* In March 2005, the Commission released a *Report and Order and Memorandum Opinion and Order* that provides for nationwide, non-exclusive licensing of terrestrial operations, utilizing contention-based technologies, in the 3650 MHz band (i.e., 3650–3700 MHz). As of April 2010, more than 1270 licenses have been granted and more than 7433 sites have been registered. The Commission has not developed a definition of small entities applicable to 3650–3700 MHz band nationwide, non-exclusive licensees. However, the Commission estimates that the majority of these licensees are Internet Access Service Providers (ISPs) and that most of those licensees are small businesses.

141. *24 GHz—Incumbent Licensees.* This analysis may affect incumbent licensees who were relocated to the 24 GHz band from the 18 GHz band, and applicants who wish to provide services in the 24 GHz band. For this service, the Commission uses the SBA small business size standard for the category “Wireless Telecommunications Carriers (except satellite),” which is 1,500 or fewer employees. To gauge small business prevalence for these cable services the Commission must, however, use the most current census

data. Census data for 2007, which supersede data contained in the 2002 Census, show that there were 1,383 firms that operated that year. Of those 1,383, 1,368 had fewer than 100 employees, and 15 firms had more than 100 employees. Thus under this category and the associated small business size standard, the majority of firms can be considered small. The Commission notes that the Census’ use of the classifications “firms” does not track the number of “licenses”. The Commission believes that there are only two licensees in the 24 GHz band that were relocated from the 18 GHz band, Teligent and TRW, Inc. It is our understanding that Teligent and its related companies have less than 1,500 employees, though this may change in the future. TRW is not a small entity. Thus, only one incumbent licensee in the 24 GHz band is a small business entity.

142. *24 GHz—Future Licensees.* With respect to new applicants in the 24 GHz band, the size standard for “small business” is an entity that, together with controlling interests and affiliates, has average annual gross revenues for the three preceding years not in excess of \$15 million. “Very small business” in the 24 GHz band is an entity that, together with controlling interests and affiliates, has average gross revenues not exceeding \$3 million for the preceding three years. The SBA has approved these small business size standards. These size standards will apply to a future 24 GHz license auction, if held.

143. *Satellite Telecommunications.* Since 2007, the SBA has recognized satellite firms within this revised category, with a small business size standard of \$15 million. The most current Census Bureau data are from the economic census of 2007, and the Commission will use those figures to gauge the prevalence of small businesses in this category. Those size standards are for the two census categories of “Satellite Telecommunications” and “Other Telecommunications.” Under the “Satellite Telecommunications” category, a business is considered small if it had \$15 million or less in average annual receipts. Under the “Other Telecommunications” category, a business is considered small if it had \$25 million or less in average annual receipts.

144. The first category of Satellite Telecommunications “comprises establishments primarily engaged in providing point-to-point telecommunications services to other establishments in the telecommunications and broadcasting

industries by forwarding and receiving communications signals via a system of satellites or reselling satellite telecommunications.” For this category, Census Bureau data for 2007 show that there were a total of 512 firms that operated for the entire year. Of this total, 464 firms had annual receipts of under \$10 million, and 18 firms had receipts of \$10 million to \$24,999,999. Consequently, the Commission estimates that the majority of Satellite Telecommunications firms are small entities that might be affected by rules adopted pursuant to the Order.

145. The second category of Other Telecommunications “primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems. Establishments providing Internet services or voice over Internet protocol (VoIP) services via client-supplied telecommunications connections are also included in this industry.” For this category, Census Bureau data for 2007 show that there were a total of 2,383 firms that operated for the entire year. Of this total, 2,346 firms had annual receipts of under \$25 million. Consequently, the Commission estimates that the majority of Other Telecommunications firms are small entities that might be affected by our action.

146. *Cable and Other Program Distribution.* Since 2007, these services have been defined within the broad economic census category of Wired Telecommunications Carriers; that category is defined as follows: “This industry comprises establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or a combination of technologies.” The SBA has developed a small business size standard for this category, which is: all such firms having 1,500 or fewer employees. According to Census Bureau data for 2007, there were a total of 955 firms in this previous category that operated for the entire year. Of this total, 939 firms had employment of 999 or fewer employees, and 16 firms had employment of 1000 employees or more. Thus, under this

size standard, the majority of firms can be considered small and may be affected by rules adopted pursuant to the Order.

147. *Cable Companies and Systems.* The Commission has developed its own small business size standards, for the purpose of cable rate regulation. Under the Commission's rules, a "small cable company" is one serving 400,000 or fewer subscribers, nationwide. Industry data indicate that, of 1,076 cable operators nationwide, all but eleven are small under this size standard. In addition, under the Commission's rules, a "small system" is a cable system serving 15,000 or fewer subscribers. Industry data indicate that, of 7,208 systems nationwide, 6,139 systems have under 10,000 subscribers, and an additional 379 systems have 10,000–19,999 subscribers. Thus, under this second size standard, most cable systems are small and may be affected by rules adopted pursuant to the Order.

148. *Cable System Operators.* The Act also contains a size standard for small cable system operators, which is "a cable operator that, directly or through an affiliate, serves in the aggregate fewer than 1 percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed \$250,000,000." The Commission has determined that an operator serving fewer than 677,000 subscribers shall be deemed a small operator, if its annual revenues, when combined with the total annual revenues of all its affiliates, do not exceed \$250 million in the aggregate. Industry data indicate that, of 1,076 cable operators nationwide, all but ten are small under this size standard. The Commission notes that it neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed \$250 million, and therefore it is unable to estimate more accurately the number of cable system operators that would qualify as small under this size standard.

149. *Open Video Services.* The open video system ("OVS") framework was established in 1996, and is one of four statutorily recognized options for the provision of video programming services by local exchange carriers. The OVS framework provides opportunities for the distribution of video programming other than through cable systems. Because OVS operators provide subscription services, OVS falls within the SBA small business size standard covering cable services, which is "Wired Telecommunications Carriers." The SBA has developed a small business size standard for this category, which is: all such firms having 1,500 or

fewer employees. According to Census Bureau data for 2007, there were a total of 955 firms in this previous category that operated for the entire year. Of this total, 939 firms had employment of 999 or fewer employees, and 16 firms had employment of 1000 employees or more. Thus, under this second size standard, most cable systems are small and may be affected by rules adopted pursuant to the Order. In addition, the Commission notes that it has certified some OVS operators, with some now providing service. Broadband service providers ("BSPs") are currently the only significant holders of OVS certifications or local OVS franchises. The Commission does not have financial or employment information regarding the entities authorized to provide OVS, some of which may not yet be operational. Thus, again, at least some of the OVS operators may qualify as small entities.

150. *Internet Service Providers.* Since 2007, these services have been defined within the broad economic census category of Wired Telecommunications Carriers; that category is defined as follows: "This industry comprises establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or a combination of technologies." The SBA has developed a small business size standard for this category, which is: all such firms having 1,500 or fewer employees. According to Census Bureau data for 2007, there were 3,188 firms in this category, total, that operated for the entire year. Of this total, 3144 firms had employment of 999 or fewer employees, and 44 firms had employment of 1000 employees or more. Thus, under this size standard, the majority of firms can be considered small. In addition, according to Census Bureau data for 2007, there were a total of 396 firms in the category Internet Service Providers (broadband) that operated for the entire year. Of this total, 394 firms had employment of 999 or fewer employees, and two firms had employment of 1000 employees or more. Consequently, the Commission estimates that the majority of these firms are small entities that may be affected by rules adopted pursuant to the Order.

151. *Internet Publishing and Broadcasting and Web Search Portals.* Our action may pertain to interconnected VoIP services, which could be provided by entities that provide other services such as email,

online gaming, web browsing, video conferencing, instant messaging, and other, similar IP-enabled services. The Commission has not adopted a size standard for entities that create or provide these types of services or applications. However, the Census Bureau has identified firms that "primarily engaged in 1) publishing and/or broadcasting content on the Internet exclusively or 2) operating Web sites that use a search engine to generate and maintain extensive databases of Internet addresses and content in an easily searchable format (and known as Web search portals)." The SBA has developed a small business size standard for this category, which is: all such firms having 500 or fewer employees. According to Census Bureau data for 2007, there were 2,705 firms in this category that operated for the entire year. Of this total, 2,682 firms had employment of 499 or fewer employees, and 23 firms had employment of 500 employees or more. Consequently, the Commission estimates that the majority of these firms are small entities that may be affected by rules adopted pursuant to the Order.

152. *Data Processing, Hosting, and Related Services.* Entities in this category "primarily . . . provid[e] infrastructure for hosting or data processing services." The SBA has developed a small business size standard for this category; that size standard is \$25 million or less in average annual receipts. According to Census Bureau data for 2007, there were 8,060 firms in this category that operated for the entire year. Of these, 7,744 had annual receipts of under \$24,999,999. Consequently, the Commission estimates that the majority of these firms are small entities that may be affected by rules adopted pursuant to the Order.

153. *All Other Information Services.* The Census Bureau defines this industry as including "establishments primarily engaged in providing other information services (except news syndicates, libraries, archives, Internet publishing and broadcasting, and Web search portals)." Our action pertains to interconnected VoIP services, which could be provided by entities that provide other services such as email, online gaming, web browsing, video conferencing, instant messaging, and other, similar IP-enabled services. The SBA has developed a small business size standard for this category; that size standard is \$7.0 million or less in average annual receipts. According to Census Bureau data for 2007, there were 367 firms in this category that operated for the entire year. Of these, 334 had

annual receipts of under \$5.0 million, and an additional 11 firms had receipts of between \$5 million and \$9,999,999. Consequently, the Commission estimates that the majority of these firms are small entities that may be affected by our action.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

154. In the Order, the Commission establishes three experiment types for which it will accept applications. The Commission allocates \$75 million to projects that must propose to deploy a network capable of delivering 100 Mbps downstream/5 Mbps upstream while offering at least one service plan that provides 25 Mbps downstream/5 Mbps upstream to all locations within the selected census blocks, with no more than 100 milliseconds (ms) of latency. Recipients must provide usage and pricing that is reasonably comparable to usage and pricing available for comparable wireline offerings (i.e., those with similar speeds in urban areas). The Commission also makes \$15 million available for projects that would offer at least one service plan that provides 10 Mbps downstream/1 Mbps upstream to all locations within the selected census blocks. This service plan must offer at least 100 GB of usage, no more than 100 ms of latency, and meet the reasonable comparability benchmarks for the pricing of voice and broadband. Finally, the Commission makes \$10 million available for projects in extremely high-cost census blocks that propose to offer at least one service plan that provides 10 Mbps downstream/1 Mbps upstream, and 100 GB of usage at a rate that meets the reasonable comparable pricing benchmarks, with latency of 100 ms, or, in the case of satellite providers, a Mean Opinion Score of four or better. If an entity wins support for one of these categories, it will be required to meet these public service obligations, or will be found in default and subject to certain compliance measures as described in the Order.

155. To participate in the rural broadband experiments, entities must submit a formal application to the Commission by no later than 90 days from the release of the Order. Entities will be required to submit confidential bids requesting a certain amount of support to serve specified census blocks (including the census block ID for each census block they propose to serve, the number of eligible locations determined by the model in each of those blocks, and the total amount of support they request). They will also be required to

provide information regarding any agreements or joint bidding arrangements with other parties, disclose any ownership interests in Commission-regulated companies, declare whether their project will serve only Tribal census blocks, submit a proposal containing basic information that will be made public if they win (e.g., background information on the applicant and its qualifications to provide voice and broadband service, a description of the proposed project, service area, planned service offerings including offerings to low-income consumers, and technology to be used; and the number of locations, including community anchor institutions, within the project area), and certify that they meet certain threshold requirements, including being in compliance with all the statutory and regulatory requirements to receive support and being financially and technically capable of meeting the required public interest obligations in each area they seek support. All entities submitting proposals must also utilize a FCC Registration Number and identify the type of project for which they are submitting a proposal.

156. Winning bidders will be required to demonstrate that they have the technical and financial qualifications to successfully complete their proposed projects within the required timeframes and that they are in compliance with all the statutory and regulatory requirements for the universal service support they seek. The Commission staff will perform a review to ensure that the applications meet our expectations for technical and financial capability. Within 10 business days of public notice of winning bidders, the winning bidders will be required to submit three consecutive years of audited financial statements (including balance sheets, net income, and cash flow), a description of the technology and system design used to deliver voice and broadband service, including a network diagram certified by a professional engineer, and a description of spectrum access in the areas for which applicants seek support for wireless technologies. Within 60 days of public notice of winning bidders, the winning bidders must submit a letter from an acceptable bank committing to issue an irrevocable stand-by original LOC. That LOC must remain open and renewed until 120 days after the end of the tenth year of the support term. Within 90 days of public notice of winning bidders, the winning bidders must provide appropriate documentation of their eligible telecommunications carrier

(ETC) designation in all areas for which they will receive support and certify that the information submitted is accurate.

157. Once a winning bidder has been found to have met the Commission's technical and financial requirements and has secured the required ETC designation and LOC commitment letter, the Bureau will release a public notice stating that the entity is ready to be authorized to receive support. Within 10 business days of this public notice, the entity must submit an irrevocable stand-by original LOC that has been issued and signed by the issuing bank along with an opinion letter from legal counsel. Once USAC has verified the sufficiency of the LOC, the Bureau will issue a public notice authorizing the entity to begin receiving support.

158. The winning bidders must meet several conditions to receive rural broadband experiment support. First, like all recipients of Connect America support, they must meet certain build-out requirements. Recipients must deploy to 85 percent of the required number of their locations within three years of their first disbursement and 100 percent of the required number of their locations within five years of their first disbursement with service meeting the service obligations required by the relevant experiment category. Entities that choose to receive 30 percent of their support upfront must meet an additional build-out requirement of 25 percent of the required number of their locations within 15 months of the first disbursement, and then must meet the same build-out requirements as recipients not requesting upfront support (85 percent of locations within three years and 100 percent within five years). All recipients must submit a certification that they have met these milestones, accompanied by evidence. The evidence may include the evidence that they submit with their November 1st build-out report, as described below.

159. Second, the Commission requires that recipients comply with several accountability measures. Like all recipients of Connect America support, they must file annual reports by July 1st of each year pursuant to § 54.313(a) of the Commission's rules, starting the first July after the year in which they begin receiving support. These reports must also include a certification regarding their compliance with the Commission's latency standard, or Mean Opinion Score, as applicable; the number, names, and addresses of the community anchor institutions to which they newly began providing access to broadband service in the preceding year; and build-out information including evidence

demonstrating which locations they have built out to in their project areas where the recipient is offering services that meet the public service obligations adopted for the relevant experiment category along with evidence that demonstrates they are meeting the public service obligations (e.g., marketing materials that detail the pricing, offered broadband speed, and data usage allowances available in the relevant geographic area).

160. To ensure that the Commission is able to monitor how experiment recipients are using their funds for their intended purposes, it also requires them to file a one-time report on November 1st of the year they begin receiving support. This report must describe the status of their project (such as whether vendors have been hired, permits have been obtained, and construction begun) and include evidence demonstrating which locations (if any) to which they have built out to in their project areas where they are offering services that meet the public service obligations for the relevant experiment category, along with evidence that the public service obligations are being met (e.g., marketing materials and a latency certification).

161. Like all recipients of Connect America support, all rural broadband experiment recipients that have been designated as ETCs by the Commission are required to file an annual certification pursuant to § 54.314 of the Commission's rules. If an entity selected for a rural broadband experiment is designated an ETC by a state, that state must file this certification on behalf of the entity selected for the rural broadband experiment. The Commission also requires recipients to certify when they have met the build-out requirements defined above. With these certifications, they must submit the same build-out information that must be included in their annual reports: Evidence demonstrating that they have built facilities to serve the required number of locations and evidence that demonstrates compliance with the relevant public service obligations, including a certification demonstrating compliance with the Commission's latency or alternative service quality requirement. All recipients are also subject to random compliance reviews, and will be subject to verification of their build-out compliance. Moreover, recipients are subject to a 10-year record retention requirement.

162. Finally, rural broadband recipients are required to cooperate with the Commission in any efforts to gather data that may help inform future

decisions regarding the impact of technology transitions on achievement of our universal access objectives.

E. Steps Taken to Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

163. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its approach, which may include the following four alternatives, among others: (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

164. The Commission adopts a streamlined application process to encourage a wide variety of entities, including small entities, to participate so that it can learn from the applications that are submitted. The Commission struck a balance between requiring enough information to prompt bidders to take appropriate steps to determine that their projects are financially viable before submitting bids, but also minimizing the resources that entities need to spend upfront in case they do not win support. The Commission does not require that entities undergo a full scale technical and financial review and obtain a LOC and ETC designation until they have been announced as winning bidders. Even after they have been announced winning bidders, the information the Commission requires to conduct such a review is information it expects winning bidders will already have on hand (e.g., audited financial statements) or will have developed as a result of planning their project (e.g., a network diagram certified by an engineer and a description of spectrum access).

165. The Commission recognizes that some entities, including small entities, may not be able to submit proposals at the census tract level, but would be interested in submitting proposals for smaller neighborhoods that they may already be well positioned to serve. The Commission waives this requirement for those entities, and permit them to submit proposals on the census block level. Recipients also have the choice of receiving 30 percent of their support upfront. This option provides the flexibility to all participating entities, including small entities, to receive more support upfront, or to receive their

support spread out over a longer period time if they are unable to meet the 15-month interim build-out deadline.

166. The Commission also adopts a bidding credit for entities, many of which may be small entities, who propose projects that will serve only Tribal census blocks. This 25 percent bidding credit will increase the likelihood that these entities will receive funding. And recognizing the unique challenges that Tribally-owned or -controlled entities may face in obtaining LOCs, the Commission also provides a waiver process for those entities that are unable to obtain a LOC.

167. The accountability measures the Commission adopts are also tailored to ensuring that rural broadband experiment support is used for its intended purpose and so that it can quickly gather data to inform our policy decisions. The measures the Commission adopts are largely the same measures that are required of all recipients of Connect America support, including annual reports and certifications. And the Commission finds that ensuring that all recipients are accountable in their use of rural broadband experiment support, including small entities, outweighs the burden of filing an extra build-out report on November 1st of their first funding year and of submitting evidence such as marketing materials to demonstrate compliance with public interest obligations with their annual reports, their November 1st build-out report, and with build-out certifications. Recipients are likely to have such information available to them as a regular course of business.

F. Report to Congress

168. The Commission will send a copy of the Report and Order, including this FRFA, in a report to be sent to Congress and the Government Accountability Office pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996. In addition, the Commission will send a copy of the Report and Order, including this FRFA, to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the Report and Order (or a summary thereof) will also be published in the **Federal Register**.

IV. Ordering Clauses

169. Accordingly, *it is ordered* that, pursuant to sections 1, 2, 4(i), 4(j), 214, 218–220, 251, 254 and 303(r) of the Communications Act of 1934, as amended, and section 706 of the Telecommunications Act of 1996, 47 U.S.C. 151, 152, 154(i), 154(j), 214, 218–220, 251, 254, 303(r), 1302 the Report

and Order in WC Docket No. 10–90 and WC Docket No. 14–58 *is adopted*, effective September 5, 2014, except for the application process and reporting requirements that contain new or modified information collection requirements that will not be effective until approved by the Office of Management and Budget. The Commission will publish a document in the **Federal Register** announcing OMB approval.

170. *It is further ordered*, that pursuant to § 1.3 of the Commission's rules, 47 CFR 1.3, the Commission waives on its own motion § 54.313(a)(1) of the Commission's rules, 47 CFR 54.313(a)(1) for all recipients of the rural broadband experiments.

171. *It is further ordered*, that the Commission *shall send* a copy of the Report and Order in WC Docket No. 10–90 and WC Docket No. 14–58 to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

172. *It is further ordered*, that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of the Report and Order in WC Docket No. 10–90 and WC Docket No. 14–58, including the Further Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison.

[FR Doc. 2014–18328 Filed 8–5–14; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 216

[Docket No. 140304190–4612–02]

RIN 0648–BE03

Subsistence Taking of Northern Fur Seals on the Pribilof Islands; Final Annual Harvest Estimates for 2014–2016

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

ACTION: Final rule; estimates of annual fur seal subsistence needs.

SUMMARY: Pursuant to the regulations governing the subsistence taking of

northern fur seals, NMFS is publishing the annual fur seal subsistence harvests on St. George and St. Paul Islands, Alaska (the Pribilof Islands) for 2011–2013 and the annual estimates of fur seal subsistence harvests for 2014–2016. NMFS estimates the annual subsistence needs for 2014–2016 are 1,645–2,000 fur seals on St. Paul and 300–500 fur seals on St. George.

DATES: Effective September 5, 2014.

ADDRESSES: More information about northern fur seal subsistence harvest management can be found on the Internet at <https://alaskafisheries.noaa.gov/protectedresources/seals/fur.htm>.

FOR FURTHER INFORMATION CONTACT:

Michael Williams, NMFS Alaska Region, 907–271–5117, Michael.Williams@noaa.gov; or Shannon Bettridge, NMFS Office of Protected Resources, 301–427–8402, Shannon.Bettridge@noaa.gov.

SUPPLEMENTARY INFORMATION:

Background

The subsistence harvest from the depleted stock of northern fur seals (*Callorhinus ursinus*), on the Pribilof Islands, AK, is governed by regulations found in 50 CFR part 216, subpart F. Pursuant to the regulations governing the taking of fur seals for subsistence purposes, NMFS must publish a summary of the fur seal harvest for the previous 3-year period and an estimate of the number of seals expected to be taken in the subsequent 3-year period to meet the subsistence needs of the Aleut residents of the Pribilof Islands. After a 30-day comment period, NMFS must publish a final notification of the expected annual harvest levels for the next 3 years.

On May 14, 2014 (79 FR 27550), NMFS published the summary of the 2011–2013 fur seal harvests and provided a 30-day comment period on the estimates of subsistence needs for 2014–2016. In that notice, NMFS estimated the annual subsistence needs for 2014–2016 would be 1,645–2,000 fur seals on St. Paul Island and 300–500 fur seals on St. George Island and provided background information related to these estimates.

Summary of Changes From Proposed Annual Harvest Estimates

NMFS did not make any changes in this final notice of annual harvest estimates. The subsistence need remains the same and therefore the annual harvest estimate remains 1,645–2,000 fur seals on St. Paul Island and 300–500 fur seals on St. George Island.

Comments and Response

NMFS received one comment letter on the notice of the 2014–2016 proposed annual harvest estimates (79 FR 27550; May 14, 2014). A summary of the comment received and NMFS's response follows.

Comment: Stop the northern fur seal harvest. The reported killings are over 2,500 animals thus the illegal kills must be about 4,500 seals.

Response: The Fur Seal Act and Marine Mammal Protection Act both provide exemptions for the subsistence harvest of northern fur seals to meet the dietary and cultural needs of the Pribilof Island Alaska Native residents (Pribilovians). The reported annual subsistence harvest of fur seals for both islands combined did not exceed 500 sub-adult fur seals during the 2011–2013 period and was well below the published subsistence need estimate of 2,500 sub-adult seals. NMFS works in partnership with the Pribilovians under co-management agreements pursuant to the Marine Mammal Protection Act to discourage and minimize illegal harvests, and NMFS's Office of Law Enforcement has a periodic presence on the Pribilof Islands to discourage, detect, and investigate any illegal harvests.

Classification

National Environmental Policy Act

NMFS prepared an Environmental Impact Statement evaluating the impacts on the human environment of the subsistence harvest of northern fur seals, which is available on the NMFS Web site (see Electronic Access).

Executive Order 12866 and Regulatory Flexibility Act

This final action is exempt from the procedures of E.O. 12866 because the action contains no implementing regulations.

The Chief Counsel for Regulation, Department of Commerce, certified to the Chief Counsel for Advocacy of the Small Business Administration that this action would not have a significant economic impact on a substantial number of small entities. The harvest of northern fur seals on the Pribilof Islands, Alaska, is for subsistence purposes only, and the estimate of subsistence need would not have an adverse economic impact on any small entities. Background information related to the certification was included in the proposed estimates published in the **Federal Register** on May 14, 2014 (79 FR 27550). We received no comments on this certification; therefore a regulatory flexibility analysis is not

required for this action, and none has been prepared.

Paperwork Reduction Act

This final action does not require the collection of information.

Executive Order 13132—Federalism

This action does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under E.O. 13132 because this action does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Nonetheless, NMFS worked closely with local governments in the Pribilof Islands, and these estimates of subsistence harvests were prepared by the local governments in St. Paul and St. George, with assistance from NMFS officials.

Executive Order 13175—Native Consultation

Executive Order 13175 of November 6, 2000 (25 U.S.C. 450 Note), the executive Memorandum of April 29, 1994 (25 U.S.C. 450 note), the American Indian Native Policy of the U.S. Department of Commerce (March 30, 1995), the Department of Commerce's Tribal Consultation Policy (including the Department of Commerce Administrative Order 218–8, April 26, 2012), and the NOAA Procedures for Government-to-Government Consultation With Federally Recognized Indian Tribes and Alaska Native Corporations (November 12, 2013) outline the responsibilities of the National Marine Fisheries Service in matters affecting tribal interests. Section 161 of Public Law 108–100 (188 Stat. 452) as amended by section 518 of Public Law 108–447 (118 Stat. 3267), extends the consultation requirements of E.O. 13175 to Alaska Native corporations. NMFS contacted the tribal governments of St. Paul and St. George Islands and their respective local Native corporations (Tanadgusix and Tanaq) about setting the next three years harvest estimates and incorporated their input.

Electronic Access

An Environmental Impact Statement, harvest reports, and other relevant information are available on the Internet at the following address: <http://alaskafisheries.noaa.gov/protectedresources/seals/fur.htm>.

Dated: July 31, 2014.

Samuel D. Rauch, III,

*Deputy Assistant Administrator for
Regulatory Programs, National Marine
Fisheries Service.*

[FR Doc. 2014–18610 Filed 8–5–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 140106011–4338–02]

RIN 0648–XD418

Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Trimester Total Allowable Catch Area Closure for the Common Pool Fishery and Possession Limit Adjustment

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

ACTION: Temporary rule; area closure and possession limit adjustment.

SUMMARY: This action closes the American plaice Trimester Total Allowable Catch Area to Northeast multispecies common pool trawl vessels for the remainder of Trimester 1, through August 31, 2014. The closure is required by regulation because the common pool fishery has caught 120 percent of its Trimester 1 quota for American plaice. This closure is intended to prevent the overharvest of the common pool's allocation for this stock. Because the common pool catch of American plaice is not limited to the American plaice Trimester Total Allowable Catch Area, this action also reduces possession and trip limit for the American plaice stock to zero for all common pool vessels through August 31, 2014, in order to prevent the overharvest of the common pool's allocation of American plaice.

DATES: This action is effective August 6, 2014, through August 31, 2014.

FOR FURTHER INFORMATION CONTACT: Liz Sullivan, Fishery Management Specialist, 978–282–8493.

SUPPLEMENTARY INFORMATION: Federal regulations at § 648.82(n)(2)(ii) require the Regional Administrator to close a common pool Trimester Total Allowable Catch (TAC) Area for a stock when 90 percent of the Trimester TAC is projected to be caught. In such cases, the Trimester TAC Area for a stock closes to all common pool vessels

fishing with gear capable of catching that stock for the remainder of the trimester. The fishing year 2014 (May 1, 2014, through April 30, 2015) common pool sub-ACL for American plaice is 24.0 mt and the Trimester 1 (May 1, 2014, through August 30, 2014) TAC is 5.8 mt. Based on the most recent data and information, which include vessel trip reports, dealer-reported landings, and vessel monitoring system information, we have determined that 120 percent of the Trimester 1 TAC was caught as of July 26, 2014. Therefore, effective August 6, 2014, the American plaice Trimester TAC Area is closed for the remainder of Trimester 1, through August 31, 2014, to all common pool vessels fishing with trawl gear. The American plaice Trimester TAC Area consists of statistical areas 512, 513, 514, 515, 521, 522, and 525. The area will reopen to common pool vessels fishing with trawl gear at the beginning of Trimester 2 on September 1, 2014.

The regulations at § 648.86(o) authorize the Regional Administrator to adjust the possession and trip limits for common pool vessels to prevent the overharvest or underharvest of the common pool quotas. Because the closure described above only applies to select areas and gear types, and because the American plaice Trimester TAC has been exceeded, additional action is necessary to prevent further overages of the Trimester TAC. Therefore, the possession and trip limit for American plaice is reduced to zero for all common pool vessels in all areas, effective August 6, 2014, through August 31, 2014.

Any overages of a trimester TAC will be deducted from Trimester 3, and any overages of the common pool's sub-ACL at the end of the fishing year will be deducted from the common pool's sub-ACL the following fishing year. Any uncaught portion of the Trimester 1 and Trimester 2 TAC will be carried over into the next trimester. Any uncaught portion of the common pool's sub-ACL may not be carried over into the following fishing year.

Weekly quota monitoring reports for the common pool fishery can be found on our Web site at: <http://www.nero.noaa.gov/ro/fso/MultiMonReports.htm>. We will continue to monitor common pool catch through vessel trip reports, dealer-reported landings, vessel monitoring system catch reports, and other available information and, if necessary, we will make additional adjustments to common pool management measures.

Classification

This action is required by 50 CFR part 648 and is exempt from review under Executive Order 12866.

The Assistant Administrator for Fisheries, NOAA, finds good cause pursuant to 5 U.S.C. 553(b)(B) and 5 U.S.C. 553(d)(3) to waive prior notice and the opportunity for public comment and the 30-day delayed effectiveness period because it would be impracticable and contrary to the public interest.

The Trimester TAC Area closure is required by regulation in order to reduce the probability of the common pool fishery exceeding its sub-ACL of American plaice. Any overages of the common pool's sub-ACLs would undermine conservation objectives and trigger the implementation of

accountability measures that would have negative economic impacts on common pool vessels. The data and information showing that American plaice had exceeded 90 percent of the Trimester 1 TAC for the stock only became available on July 26, 2014. The time necessary to provide for prior notice and comment, and a 30-day delay in effectiveness, would prevent NMFS from implementing the necessary Trimester TAC Area closure for American plaice in a timely manner, which could undermine management objectives of the Northeast Multispecies Fishery Management Plan, and cause negative economic impacts to the common pool fishery.

Additionally, the overage in the American plaice Trimester 1 TAC increases the probability of the common

pool exceeding its sub-ACL of American plaice by more than it already has. The time necessary to provide for prior notice and comment, and a 30-day delay in effectiveness, would prevent NMFS from setting the possession and trip limit to zero for American plaice in a timely manner, which could also undermine management objectives of the Northeast Multispecies Fishery Management Plan, and cause negative economic impacts to the common pool fishery.

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

Dated: July 31, 2014.

Emily H. Menashes,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2014-18513 Filed 7-31-14; 4:15 pm]

BILLING CODE 3510-22-P

Proposed Rules

Federal Register

Vol. 79, No. 151

Wednesday, August 6, 2014

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF ENERGY

[Docket No. EERE-2011-BT-CE-0077]

10 CFR Part 460

Appliance Standards and Rulemaking Federal Advisory Committee (ASRAC)—Regional Standards Enforcement Working Group

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

ACTION: Notice of open meeting.

SUMMARY: This notice announces an open meeting for the Regional Standards Enforcement Working Group (RSE Working Group). The purpose of the working group will be to discuss and, if possible, reach consensus on a proposed rule for the energy efficiency of requirements of enforcement of regional standards, as authorized by the Energy Policy and Conservation Act (EPCA) of 1975, as amended.

DATES: A two-day, open meeting will be held on:

Wednesday, August 13; 9 a.m.–5 p.m. (EDT) and

Thursday, August 14; 9 a.m.–5 p.m. (EDT).

Foreign nationals wishing to participate in the meeting must respond by email to asrac@ee.doe.gov as soon as possible, to initiate the necessary security screening procedures.

ADDRESSES: Wednesday: U.S. Department of Energy, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, Room 8E-089. Thursday: 950 L'Enfant Plaza Washington, DC 20024, room 6097/8/9. Individuals will also have the opportunity to participate by webinar.

Webinar: To register for the webinar and receive call-in information, please register for Wednesday, August 13 at <https://www1.gotomeeting.com/register/831773864> and for Thursday, August 14 at <https://www1.gotomeeting.com/register/916598880>.

FOR FURTHER INFORMATION CONTACT: Ashley Armstrong, Lead Project

Manager, Building Technologies Office, Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy (DOE), 950 L'Enfant Plaza SW., Washington, DC 20024. Phone: 202–586–6590; Email: asrac@ee.doe.gov.

SUPPLEMENTARY INFORMATION:

Purpose of Meeting

The purpose of the working group will be to discuss and, if possible, reach consensus on a proposed rule for the enforcement of regional energy efficiency standards for split-system central air conditioners and single-package central air conditioners, as authorized by the Energy Policy and Conservation Act (EPCA) of 1975, as amended.

Tentative Agenda: (Subject to change):

- Overview of Working Group's Task
- Discussion and formation of a work plan for the RSE Working Group to accomplish its objectives.

Public Participation

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 visiting DOE Headquarters are subject to advance security screening procedures. Any foreign national wishing to participate in the meeting should advise ASRAC staff as soon as possible by emailing asrac@ee.doe.gov to initiate the necessary procedures, *as soon as possible*. 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.

Members of the public will be heard in the order in which they request to make a statement at the public meeting. Time allotted per speaker will depend on the number of individuals who wish to speak but will not exceed five minutes. Reasonable provision will be made to include the scheduled oral statements on the agenda. The co-chairs

of the Committee will make every effort to hear the views of all interested parties and to facilitate the orderly conduct of business.

Participation in the meeting is not a prerequisite for submission of written comments. ASRAC invites written comments from all interested parties during the course of the negotiations. If you would like to file a written statement with the committee, you may do so either by submitting a hard or electronic copy before or after the meeting. Electronic copy of written statements should be emailed to asrac@ee.doe.gov.

Minutes: All notices, public comments, public meeting transcripts, and supporting documents associated with this working group are included in Docket No. EERE-2011-BT-CE-0077.

Issued in Washington, DC, on July 31, 2014.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2014–18567 Filed 8–5–14; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Parts 234, 244, 250, 255, 256, 257, 259, and 399

[Docket No. DOT-OST-2014-0056]

RIN 2105-AE11

Transparency of Airline Ancillary Fees and Other Consumer Protection Issues

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Extension of comment period on proposed rule.

SUMMARY: This action extends the comment period for an NPRM on transparency of airline ancillary fees and other consumer protection issues that was published in the **Federal Register** on May 23, 2014. The Department of Transportation is extending the period for interested persons to submit comments on this rulemaking from August 21, 2014, to September 22, 2014. This extension is a result of a joint petition filed by a number of airline associations to extend the comment period for the proposal.

DATES: Comments must be received by September 22, 2014. Comments received after this date will be considered to the extent practicable.

ADDRESSES: You may file comments identified by the docket number DOT–OST–2014–0056 by any of the following methods:

- *Federal eRulemaking Portal:* go to <http://www.regulations.gov> and follow the online instructions for submitting comments.

- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE., Room W12–140, Washington, DC 20590–0001.

- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE., between 9:00a.m. and 5:00p.m. ET, Monday through Friday, except Federal Holidays.

- *Fax:* (202) 493–2251.

Instructions: You must include the agency name and docket number DOT–OST–2014–0056 or the Regulatory Identification Number, RIN No. 2105–AE11, for the rulemaking at the beginning of your comment. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Privacy Act: Anyone is able to search the electronic form of all comments received in any of our dockets by the name of the individual submitting the comment (or signing the comment if submitted on behalf of an association, a business, a labor union, etc.). You may review DOT’s complete Privacy Act statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit <http://DocketsInfo.dot.gov>.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or to the street address listed above. Follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT:

Kimberly Graber or Blane A. Workie, Office of the Assistant General Counsel for Aviation Enforcement and Proceedings, U.S. Department of Transportation, 1200 New Jersey Ave. SE., Washington, DC 20590, 202–366–9342 (phone), 202–366–7152 (fax), Kimberly.graber@dot.gov or blane.workie@dot.gov (email).

SUPPLEMENTARY INFORMATION: On May 23, 2014, the Department published a Notice of Proposed Rulemaking (NPRM) on transparency of airline ancillary fees and other consumer protection issues, including clarifying and codifying the Department’s interpretation of the

statutory definition of “ticket agent;” expanding the pool of “reporting” carriers; requiring enhanced reporting by mainline carriers for their domestic code-share partner operations; requiring large travel agents to adopt minimum customer service standards; codifying the statutory requirement that carriers and ticket agents disclose any airline code-share arrangements on their Web sites; and prohibiting unfair and deceptive practices such as undisclosed biasing in schedule and fare displays and post-purchase price increases. Additionally, this NPRM would correct drafting errors and make minor changes to the Department’s second Enhancing Airline Passenger Protections rule to conform to guidance issued by the Department’s Office of Aviation Enforcement and Proceedings (Enforcement Office) regarding its interpretation of the rule. See 79 FR 29970 (May 23, 2014). Comments on the matters proposed were to be received 90 days after publication of the NPRM, or by August 21, 2014.

We received a joint petition for a 90-day extension of the comment period for this rulemaking by Airlines for America (A4A), the International Air Transportation Association (IATA), and the Regional Airline Association (RAA). According to this petition, the extension is appropriate because the NPRM proposes significant new regulations on U.S. and foreign carriers and ticket agents, in addition to requesting information and views on dozens of topics that could materially alter the proposal. The petitioners also state that the proposed rule would expand the regulated community by covering previously unregulated entities and commercial relationships. Further, the petitioners point out that the Regulatory Impact Analysis (RIA) accompanying the NPRM requests information on a number of proposals and alternatives and more time is needed to provide the Department with the extensive information it requests.

We received four comments generally in support of this joint petition. Spirit Airlines supports the joint petition and its underlying rationale. Airline Tariff Publishing Company (ATPCO) also agrees with the petition particularly because of the complex technical questions raised by the NPRM in relation to implementing the proposal of enhancing transparency in airline ancillary fees. Open Allies for Airfare Transparency urges the Department not to prolong the adoption of a rule that would enhance airline pricing transparency but also recognizes the complexity of the proposals in this NPRM. Therefore, it supports a

“reasonable extension” period of less than 90 days. Travelers United opposes any extension to the comment period for the proposal to enhance transparency of ancillary fees and states that this topic has been debated and commented for three years. It also opposes an extension to the comment period proposals related to reporting issues. Also recognizing the complexity of the NPRM, Travelers United supports a limited extension to the comment period for other topics such as codifying the definition of ticket agent, requiring large travel agents to adopt customer service standards, transparency of codeshare operations, and disclosure of biasing in schedule and fare displays.

While we concur with the requests for an extension of the comment period, we believe that a 90-day extension would be excessive. We have decided to grant an extension of 30 days, or until September 22, 2014, for the public to comment on the NPRM. We believe this extension is appropriate in balancing the need for additional time for comments and the need to proceed expeditiously with this important rulemaking. We note that the proposal to enhance airline ancillary fee transparency, which is the proposal in this NPRM that involves the most technical complexities, was one of the proposals in the Department’s 2010 Enhancing Airline Passenger Protection rulemaking. In the final rule of that rulemaking, we deferred final action on this matter to a future rulemaking. Therefore, the interested parties have been on notice that we intended to further explore this topic in a subsequent rulemaking. We further note that with this additional 30 days we are granting here, interested parties will have total of 120 days to comment on the proposals, which we believe is adequate time for analysis and coordination regarding the proposals.

Accordingly, the Department finds that good cause exists to extend the time for comments on the proposed rule from August 21, 2014, to September 22, 2014. We do not anticipate any further extension of the comment period for this rulemaking.

Issued this 31st day of July, 2014, in Washington, DC.

Kathryn B. Thomson,

General Counsel, Office of Regulation and Enforcement, U.S. Department of Transportation.

[FR Doc. 2014–18525 Filed 8–5–14; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52****[EPA-R04-OAR-2012-0798; FRL-9914-79-OAR]****Approval and Promulgation of Implementation Plans; Mississippi: New Source Review (NSR)-Prevention of Significant Deterioration (PSD)****AGENCY:** Environmental Protection Agency.**ACTION:** Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve portions of a revision to the Mississippi State Implementation Plan (SIP) submitted by the State of Mississippi, through the Mississippi Department of Environmental Quality (MDEQ), on February 10, 2012. The SIP revision modifies Mississippi's New Source Review (NSR) Prevention of Significant Deterioration (PSD) program to incorporate by reference (IBR) certain Federal PSD regulations. EPA is proposing to approve these portions of Mississippi's SIP revision because the Agency has preliminarily determined that they are consistent with the Clean Air Act (CAA or Act) and EPA's NSR permitting regulations.

DATES: Comments must be received on or before September 5, 2014.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R04-OAR-2012-0798 by one of the following methods:

1. *www.regulations.gov*: Follow the on-line instructions for submitting comments.
2. *Email*: R4-RDS@epa.gov.
3. *Fax*: (404) 562-9019.
4. *Mail*: EPA-R04-OAR-2012-0798, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960.
5. *Hand Delivery or Courier*: Ms. Lynorae Benjamin, Chief, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's 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-R04-OAR-2012-

0798." 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 through *www.regulations.gov* or email, information that you consider to be CBI or otherwise protected. 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. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are

Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: For information regarding the Mississippi SIP, contact Ms. Twunjala Bradley, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. Ms. Bradley's telephone number is (404) 562-9352; email address: *bradley.twunjala@epa.gov*.

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- I. What action is EPA proposing?
- II. What is the background for EPA's proposed action?
- III. What is EPA's analysis of Mississippi's SIP revision?
- IV. Proposed Action
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I. What action is EPA proposing?

On February 10, 2012, MDEQ submitted a SIP revision to EPA for approval into the Mississippi SIP that includes changes to the State's Air Quality Regulations in Air Pollution Control, Section 5 (APC-S-5)—*Regulations for the Prevention of Significant Deterioration of Air Quality*. These rule changes were provided to comply with Federal NSR PSD permitting requirements. The February 10, 2012, SIP submission updates the IBR¹ date in APC-S-5 to November 4, 2011, for the Federal PSD permitting regulations at 40 CFR 52.21 and portions of 51.166 to include PSD provisions promulgated in the carbon dioxide (CO₂) Biomass Deferral Rule,² PM₁₀ Surrogate and Grandfather Policy Repeal,³ and Reasonable Possibility Rule.⁴ EPA is not proposing to approve the portion of Mississippi's SIP submission that IBR the July 20, 2011 CO₂ Biomass Deferral Rule because the United States Court of Appeals for the District of Columbia Circuit (D.C.

¹ Throughout this rulemaking the acronym IBR means "incorporate by reference" or "incorporates by reference."

² "Deferral for CO₂ Emissions From Bioenergy and Other Biogenic Sources Under the Prevention of Significant Deterioration (PSD) and Title V Programs," Final Rule, 76 FR 43490, (July 20, 2011) (hereinafter referred to as the CO₂ Biomass Deferral Rule).

³ Implementation of the New Source Review (NSR) Program for Particulate Matter Less than 2.5 Micrometers (PM_{2.5}); Final Rule to Repeal Grandfather Provision" Final Rule, 76 FR 28646, (May 18, 2011) (hereinafter referred to as the PM₁₀ Surrogate and Grandfather Policy Repeal).

⁴ "Prevention of Significant Deterioration and Nonattainment New Source Review: Reasonable Possibility in Recordkeeping" Final Rule, 72 FR 72607, (December 21, 2007) (hereinafter referred to as the Reasonable Possibility Rule).

Circuit) issued a decision on July 12, 2013, in *Center for Biological Diversity v. EPA*, 722 F.3d 401 (D.C. Cir. 2013) to vacate the rule. Today, EPA is proposing to approve only the portions of Mississippi's February 10, 2012, SIP revision addressing the Reasonable Possibility Rule and the PM₁₀ Surrogate and Grandfather Policy Repeal Rule.⁵

II. What is the background for EPA's proposed action?

Today's proposed action to revise the Mississippi SIP relates to PSD provisions promulgated in the PM₁₀ Surrogate and Grandfather Policy Repeal and the Reasonable Possibility Rule. More details regarding these rules are found in the respective final rulemakings and are summarized below.

A. Reasonable Possibility Rule

On June 24, 2005, the D.C. Circuit issued a decision on the challenges to the 2002 NSR Reform Rules including reasonable possibility. *New York v. U.S. EPA*, 413 F.3d 3 (D.C. Cir. 2005).⁶ For additional information on the 2002 NSR Reform Rules, see 67 FR 80186 (December 31, 2002) and <http://www.epa.gov/nsr>.

In summary, the D.C. Circuit remanded a portion of the rules regarding recordkeeping and the term "reasonable possibility" found in 40 CFR 52.21(r)(6) and 40 CFR 51.165(a)(6)

and 51.166(r)(6) requiring that EPA either provide an acceptable explanation for its "reasonable possibility" standard or devise an appropriate alternative. In response to the court's decision, EPA took final action on December 21, 2007, to clarify that a "reasonable possibility" applies where source emissions equal or exceed 50 percent of the CAA NSR significance levels for any pollutant. See 72 FR 72607. The "reasonable possibility" provision identifies for sources and reviewing authorities the circumstances under which a major stationary source undergoing a modification that does not trigger major NSR must keep records. EPA's December 21, 2007, final rule on the record-keeping and reporting provisions also explains state obligations with regard to the reasonable possibility related rule changes.⁷ See 72 FR 72607 at 72613–14. The final rule gave states and local permitting authorities three years from publication to submit revisions to incorporate the reasonable possibility provisions or to submit notice to EPA that their regulations fulfill these requirements.

MDEQ adopted the NSR Reform rules in the SIP on July 28, 2005, however, MDEQ did not incorporate the "reasonable possibility" provision at that time due to the remand. In its 2005 PSD regulations at APC–S–5 (2.6), MDEQ excluded the following phrase from its IBR of 40 CFR 52.21: "in circumstances where there is a reasonable possibility, within the meaning of paragraph (r)(6)(vi) of 40 CFR 52.21, that a project that is not a part of a major modification may result in a significant emissions increase." On July 10, 2006, EPA published the final rulemaking approving Mississippi's SIP revision adopting the NSR Reform Rule. See 71 FR 38773. In the approval, EPA acknowledged Mississippi's rule did not contain the reasonable possibility language that was included in the remand and stated, "EPA continues to move forward with its evaluation of the portion of its NSR reform rules that were remanded by the D.C. Circuit and is preparing to respond to the D.C. Circuit's remand. EPA's final decision

with regard to the remand may require EPA to take further action on this portion of Mississippi's rules."

B. PM₁₀ Surrogate and Grandfather Policy Repeal

In the NSR PM_{2.5} Rule,⁸ EPA finalized regulations to establish the framework for implementing preconstruction permit review for the PM_{2.5} NAAQS in both attainment and nonattainment areas. This rule included a grandfather provision that allowed PSD applicants that submitted their complete permit application prior to the July 15, 2008, effective date of the NSR PM_{2.5} Rule to continue to rely on the 1997 PM₁₀ Surrogate Policy rather than amend their application to demonstrate compliance directly with the new PM_{2.5} requirements. See 73 FR 28321. On May 12, 2011, Mississippi submitted a SIP revision that excluded the PM₁₀ surrogate grandfathering provision at 40 CFR 52.21(i)(1)(xi) from the state's PSD regulations. EPA approved portions of Mississippi's May 12, 2011, SIP revision on September 26, 2012 (77 FR 59095). On May 18, 2011, EPA took final action to repeal the PM_{2.5} grandfathering provision at 40 CFR 52.21(i)(1)(xi). See 76 FR 28646.

III. What is EPA's analysis of Mississippi's SIP revision?

MDEQ's PSD preconstruction rules are found at Mississippi Rule APC–S–5-*Regulations for Prevention of Significant Deterioration for Air Quality* and apply to major stationary sources or modifications constructed in areas designated attainment areas or unclassifiable/attainment areas as required under part C of title I of the CAA with respect to the NAAQS. MDEQ's February 10, 2012, SIP submittal updates the IBR date in APC–S–5 to November 4, 2011, for the Federal PSD permitting regulations at 40 CFR 52.21 to include the Federal PSD permitting updates promulgated in the CO₂ Biomass Deferral Rule, the Reasonable Possibility Rule, and the PM₁₀ Surrogate and Grandfather Policy Repeal. EPA is proposing to approve the updates only as they relate to the Reasonable Possibility Rule and the PM₁₀ Surrogate and Grandfather Policy

⁵ Mississippi's February 10, 2012, SIP submission only addresses the adoption of the three PSD permitting regulations discussed above that the State requested for inclusion into the SIP. Any previous SIP revisions submitted by MDEQ that adopted other PSD permitting provisions captured in 40 CFR 52.21 as of November 4, 2011, were addressed by EPA in separate actions and are not relevant to the State's February 10, 2012, submission or to today's proposed approval into the SIP of the Reasonable Possibility Rule and the PM₁₀ Surrogate and Grandfather Policy Repeal Rule PSD permitting provisions discussed in this rulemaking.

⁶ On December 31, 2002 (67 FR 80186), EPA published final rule changes to 40 CFR parts 51 and 52 regarding the CAA's PSD and nonattainment new source review programs. On November 7, 2003 (68 FR 63021), EPA published a notice of final action on the reconsideration of the December 31, 2002, final rule changes. The December 31, 2002, and the November 7, 2003, final actions are collectively referred to as the "2002 NSR Reform Rules." After the 2002 NSR Reform Rules were finalized and effective (March 3, 2003), industry, state, and environmental petitioners challenged numerous aspects of the 2002 NSR Reform Rules, along with portions of EPA's 1980 NSR Rules, 45 FR 52676 (August 7, 1980). In summary, the D.C. Circuit vacated portions of the rules pertaining to clean units and PCPs, remanded a portion of the rules regarding recordkeeping and the term "reasonable possibility" found in 40 CFR 52.21(r)(6) and 40 CFR 51.165(a)(6) and 51.166(r)(6), and either upheld or did not comment on the other provisions included as part of the 2002 NSR Reform Rules. On June 13, 2007 (72 FR 32526), EPA took final action to revise the 2002 NSR Reform Rules to remove from Federal law all provisions pertaining to clean units and the PCPs exemption that were vacated by the DC Circuit.

⁷ On January 14, 2009, EPA denied a petition by the State of New Jersey (submitted February 15, 2008) for reconsideration and stay of the December 21, 2007, final rule for "reasonable possibility." However, on March 11, 2009, New Jersey reiterated its request for reconsideration, which EPA granted on April 24, 2009. EPA has not taken action on the reconsideration; therefore, the current recordkeeping rules established in the December 21, 2007, final rule are approvable. See <http://www.epa.gov/nsr/actions.html#2009> under *Denial of Petitions to Reconsider Aspects of the PM_{2.5} NSR Requirements and Reasonable Possibility Rule* for additional information on the New Jersey petition.

⁸ This rulemaking established regulations to implement the NSR program for the PM_{2.5} NAAQS on May 16, 2008. See 73 FR 28321. As a result of EPA's final NSR PM_{2.5} Rule, states were required to submit SIP revisions to EPA no later than May 16, 2011, to address these requirements for both the PSD and NNSR programs. On May 12, 2011, Mississippi submitted a SIP revision to IBR the NSR PM_{2.5} Rule into the state's SIP at APC–S–5. EPA approved portions of the NSR PM_{2.5} rule into the Mississippi SIP PSD program on September 26, 2012. See 77 FR 59095.

Repeal. EPA is not proposing to approve the portion of Mississippi's February 10, 2012, SIP submission that IBR the CO₂ Biomass Deferral Rule at APC-S-5 as a result of the July 12, 2013, court decision identified above. EPA may address this portion of Mississippi's SIP submission in a separate rulemaking.

Regarding reasonable possibility, the February 10, 2012, SIP revision removes the reasonable possibility exclusion at APC-S-5(2.6) and IBR EPA's December 21, 2007, revised definition of reasonable possibility into its SIP.

Mississippi's February 10, 2012, SIP revision also adopts the repeal of the PM_{2.5} Grandfathering Provision. Mississippi's February 10, 2012, SIP submittal incorporates into the Mississippi SIP the version of 40 CFR 52.21 as of November 4, 2011, which includes the May 18, 2011, repeal of the grandfather provision. Thus, the language previously approved into Mississippi SIP at APC-S-5(2.7) that excludes the grandfathering provision is no longer necessary. Mississippi's February 10, 2012, SIP submittal removes the unnecessary language pertaining to the grandfather provision from APC-S-5.

IV. Proposed Action

EPA is proposing to approve portions of Mississippi's February 10, 2012, SIP submission that update the IBR date in APC-S-5 to November 4, 2011, for the Federal PSD permitting regulations at 40 CFR 52.21 to include the Reasonable Possibility Rule and the PM₁₀ Surrogate and Grandfather Policy Repeal. EPA has made the preliminary determination that these portions of the SIP revision are approvable because they are consistent with section 110 of the CAA and EPA PSD permitting regulations.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed 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 proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);

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

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

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

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

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

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

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

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

In addition, this proposed rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Particulate matter, Reporting and recordkeeping requirements.

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

Dated: July 28, 2014.

Heather McTeer Toney,
Regional Administrator, Region 4.

[FR Doc. 2014-18625 Filed 8-5-14; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA-R03-OAR-2014-0148; FRL-9914-71-Region 3]

Approval and Promulgation of Air Quality Implementation Plans; District of Columbia, Maryland, and Virginia; Approval of the Redesignation Requests and Maintenance Plan of the Washington, DC-MD-VA Nonattainment Area for the 1997 Annual Fine Particulate Matter Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve the requests from the District of Columbia (the District), the State of Maryland (Maryland), and the Commonwealth of Virginia (Virginia) (collectively "the States") to redesignate to attainment their respective portions of the Washington, DC-MD-VA nonattainment area (hereafter "the Washington Area" or "the Area") for the 1997 annual fine particulate matter (PM_{2.5}) National Ambient Air Quality Standard (NAAQS or standard). EPA is also proposing to approve as a revision to their respective State Implementation Plans (SIPs) the common maintenance plan submitted by the States to show maintenance of the 1997 annual PM_{2.5} NAAQS through 2025 for the Washington Area. The Washington Area maintenance plan includes motor vehicle emissions budgets (MVEBs) for PM_{2.5} and nitrogen oxides (NO_x) for the Area for the 1997 annual PM_{2.5} standard, which EPA is proposing to approve for transportation conformity purposes. These actions are being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before September 5, 2014.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA-R03-OAR-2014-0148 by one of the following methods:

A. www.regulations.gov. Follow the on-line instructions for submitting comments.

B. Email: Fernandez.cristina@epa.gov.

C. Mail: EPA-R03-OAR-2014-0148, Cristina Fernández, Associate Director, Office of Air Quality Planning, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. Hand Delivery: At the previously-listed EPA Region III address. Such

deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-R03-OAR-2014-0148. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or email. The www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through www.regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittals are available at District of Columbia, Department of the Environment, Air Quality Division, 1200 1st Street NE., 5th floor, Washington, DC 20002; Maryland Department of the Environment, 1800 Washington

Boulevard, Suite 705, Baltimore, Maryland 21230; and Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219, respectively.

FOR FURTHER INFORMATION CONTACT: Emlyn Vélez-Rosa, (215) 814-2038, or by e-mail at velez-rosa.emlyn@epa.gov.

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I. Background

The first air quality standards for PM_{2.5} were established on July 16, 1997 (62 FR 38652, July 18, 1997). EPA promulgated an annual standard at a level of 15 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$), based on a three-year average of annual mean PM_{2.5} concentrations (the 1997 annual PM_{2.5} standard). In the same rulemaking action, EPA promulgated a 24-hour standard of 65 $\mu\text{g}/\text{m}^3$, based on a three-year average of the 98th percentile of 24-hour concentrations.

On January 5, 2005 (70 FR 944, 1014), EPA published air quality area designations for the 1997 PM_{2.5} standards. In that rulemaking action, EPA designated the Washington Area as nonattainment for the 1997 annual PM_{2.5} standard. The Washington Area includes the entire District of Columbia; Arlington, Fairfax, Loudoun, and Prince William Counties and the cities of Alexandria, Fairfax, Falls Church, Manassas, and Manassas Park in Virginia; and Charles, Frederick, Montgomery, and Prince George's Counties in Maryland. See 40 CFR 81.309, 81.321, and 81.347.

On October 17, 2006 (71 FR 61144), EPA retained the annual average standard at 15 $\mu\text{g}/\text{m}^3$, but revised the 24-hour standard to 35 $\mu\text{g}/\text{m}^3$, based again on the three-year average of the 98th percentile of 24-hour concentrations (the 2006 24-hour PM_{2.5} standard). On

November 13, 2009 (74 FR 58688), EPA published designations for the 2006 24-hour PM_{2.5} standard, which became effective on December 14, 2009. The Washington Area was not designated as a nonattainment area for the 2006 24-hour PM_{2.5} NAAQS.

In response to legal challenges of the 2006 annual PM_{2.5} standard, the United States Court of Appeals for the District of Columbia (DC Circuit Court) remanded this standard to EPA for further consideration. See *American Farm Bureau Federation and National Pork Producers Council, et al. v. EPA*, 559 F.3d 512 (D.C. Cir. 2009). However, given that the 1997 annual and the 2006 annual PM_{2.5} standards are essentially identical, attainment of the 1997 annual PM_{2.5} standard would also indicate attainment of the remanded 2006 annual PM_{2.5} standard. Since the Washington Area is designated nonattainment only for the 1997 annual PM_{2.5} NAAQS, today's proposed rulemaking action addresses the redesignation to attainment only for this standard.

On January 12, 2009 (74 FR 1146), EPA determined that the entire Washington Area had attained the 1997 annual PM_{2.5} standard, based on 2004–2006 and 2005–2007 quality-assured, quality-controlled, and certified ambient air quality monitoring data. Pursuant to 40 CFR 51.1004(c), this "clean data" determination suspended the requirements for each of the States to submit for their jurisdiction of the Washington Area an attainment demonstration and associated reasonably available control measures (RACM), a reasonable further progress (RFP) plan, contingency measures, and other planning SIP revisions related to the attainment of the 1997 annual PM_{2.5} NAAQS until such time as: (1) The Area is redesignated to attainment for the standard, at which time the requirements no longer apply; or (2) EPA determines that the Area has again violated the standard, at which time such plans are required to be submitted by the States. Subsequently, on January 10, 2012 (77 FR 1411), EPA determined, pursuant to section 179(c), that the entire Washington Area had attained the 1997 annual PM_{2.5} NAAQS by its statutory attainment date of April 5, 2010.

The District of Columbia Department of the Environment (DDOE), the Maryland Department of the Environment (MDE), and the Virginia Department of Environmental Quality (VADEQ) worked together in developing a combined document to address the requirements for redesignation of the Washington Area for the 1997 annual PM_{2.5} NAAQS. The States also

developed a common maintenance plan as a revision to their respective SIPs to ensure continued attainment of the 1997 annual PM_{2.5} standard in the Washington Area throughout 2025. The 1997 annual PM_{2.5} redesignation requests and maintenance plans for the Washington Area were submitted to EPA by DDOE on June 3, 2013, by MDE on July 10, 2013, and by VADEQ on June 3, 2013. The emissions inventories included in the Washington Area maintenance plans were subsequently supplemented by the States to provide for emissions estimates of VOC and ammonia. The supplemental inventories were submitted to EPA on July 22, 2013 by DDOE, on July 26, 2013 by MDE, and on July 17, 2013 by VADEQ. In addition, the maintenance plan includes the 2017 and 2025 PM_{2.5} and NO_x MVEBs used for transportation conformity purposes for the entire Washington Area for the 1997 annual PM_{2.5} NAAQS.

II. EPA's Requirements

A. Criteria for Redesignation to Attainment

The CAA provides the requirements for redesignating a nonattainment area to attainment. Specifically, section 107(d)(3)(E) of the CAA allows for redesignation providing that: (1) EPA determines that the area has attained the applicable NAAQS; (2) EPA has fully approved the applicable implementation plan for the area under section 110(k); (3) EPA determines that the improvement in air quality is due to permanent and enforceable reductions in emissions resulting from implementation of the applicable SIP and applicable Federal air pollutant control regulations and other permanent and enforceable reductions; (4) EPA has fully approved a maintenance plan for the area as meeting the requirements of section 175A of the CAA; and (5) the state containing such area has met all requirements applicable to the area under section 110 and part D.

EPA has provided guidance on redesignation in the "State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990," (57 FR 13498, April 16, 1992) (the "General Preamble") and has provided further guidance on processing redesignation requests in the following documents: (1) "Procedures for Processing Requests to Redesignate Areas to Attainment," Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992 (hereafter the "1992 Calcagni Memorandum"); (2) "State Implementation Plan (SIP) Actions

Submitted in Response to Clean Air Act (CAA) Deadlines," Memorandum from John Calcagni, Director, Air Quality Management Division, October 28, 1992; and (3) "Part D New Source Review (Part D NSR) Requirements for Areas Requesting Redesignation to Attainment," Memorandum from Mary D. Nichols, Assistant Administrator for Air and Radiation, October 14, 1994.

B. Requirements of a Maintenance Plan

Section 175A of the CAA sets forth the elements of a maintenance plan for areas seeking redesignation from nonattainment to attainment. Under section 175A, the plan must demonstrate continued attainment of the applicable NAAQS for at least 10 years after approval of a redesignation of an area to attainment. Eight years after the redesignation, the state must submit a revised maintenance plan demonstrating that attainment will continue to be maintained for the 10 years following the initial 10-year period. To address the possibility of future NAAQS violations, the maintenance plan must contain such contingency measures, with a schedule for implementation, as EPA deems necessary to assure prompt correction of any future PM_{2.5} violations.

The 1992 Calcagni Memorandum provides additional guidance on the content of a maintenance plan. The memorandum states that a maintenance plan should address the following provisions: (1) An attainment emissions inventory; (2) a maintenance demonstration showing maintenance for 10 years; (3) a commitment to maintain the existing monitoring network; (4) verification of continued attainment; and (5) a contingency plan to prevent or correct future violations of the NAAQS.

III. Summary of Proposed Actions

EPA is proposing to take several rulemaking actions related to the redesignation of the Washington Area to attainment for the 1997 annual PM_{2.5} NAAQS. First, EPA is proposing to find that the States meet the requirements for redesignation of the Washington Area for the 1997 annual PM_{2.5} NAAQS under section 107(d)(3)(E) of the CAA. Second, EPA is proposing to approve the Washington Area's maintenance plan for the Area as a revision to the District, Virginia, and Maryland SIPs for the 1997 annual PM_{2.5} NAAQS. The approval of a maintenance plan is one of the CAA criteria for redesignation of the Area to attainment. The Washington Area maintenance plan is designed to ensure continued attainment of the 1997 annual PM_{2.5} standard in the entire Area for 10 years after redesignation, until

2025. Third, EPA is proposing to approve the MVEBs for PM_{2.5} and NO_x emissions for the 1997 annual PM_{2.5} standard, which are included as part of the Washington Area's maintenance plan. EPA previously determined that the Washington Area has attained the 1997 annual PM_{2.5} NAAQS. In this rulemaking action, EPA is proposing to find that the Area continues to attain the standard.

IV. Effect of Recent Court Decisions on Proposed Actions

In this proposed rulemaking action, EPA considers the effects of three legal decisions on this redesignation. EPA first considers the effects of the D.C. Circuit and U.S. Supreme Court's decisions in *EME Homer City Generation, L.P. v. EPA*, 696 F.3d 7 (D.C. Cir. 2012), *rev'd*, No. 12–1182 (S. Ct. April 29, 2014). The Supreme Court reversed the D.C. Circuit decision vacating and remanding the Cross-State Air Pollution Rule (CSAPR). Second, EPA is considering the effect of the January 4, 2013, D.C. Circuit decision remanding to EPA the "Final Clean Air Fine Particle Implementation Rule" (72 FR 20586, April 25, 2007) and the "Implementation of the New Source Review (NSR) Program for Particulate Matter Less than 2.5 Micrometers (PM_{2.5})" final rule (73 FR 28321, May 16, 2008) (collectively, "1997 PM_{2.5} Implementation Rule"). *Natural Resources Defense Council (NRDC) v. EPA*, 706 F.3d 428 (D.C. Cir. 2013).

A. Effect of the Supreme Court and D.C. Circuit's Decisions Regarding EPA's CSAPR

EPA has considered the recent decisions from the U.S. Supreme Court and the D.C. Circuit Court regarding EPA's CSAPR, and has concluded that the decisions do not alter the Agency's proposal to redesignate the Washington Area from nonattainment to attainment for the 1997 annual PM_{2.5} NAAQS. EPA promulgated CSAPR (76 FR 48208, August 8, 2011) to replace the Clean Air Interstate Rule (CAIR), which has been in place since 2005. *See* 76 FR 59517. Both CSAPR and CAIR require significant reductions in emissions of SO₂ and NO_x from electric generating units (EGUs) to limit the interstate transport of these pollutants and the ozone and fine particulate matter they form in the atmosphere. The DC Circuit Court initially vacated CAIR, *North Carolina v. EPA*, 531 F.3d 896 (D.C. Cir. 2008), but ultimately remanded the rule to EPA without vacatur to preserve the environmental benefits provided by CAIR, *North Carolina v. EPA*, 550 F.3d 1176, 1178 (D.C. Cir. 2008). After

staying the implementation of CSAPR on December 20, 2011 and instructing EPA to continue to implement CAIR in the interim, on August 21, 2012, the D.C. Circuit Court issued a decision to vacate CSAPR, with further instruction to continue administering CAIR “pending the promulgation of a valid replacement.” *EME Homer City Generation L.P. v. EPA*, 696 F.3d 7, 38 (D.C. Cir. 2012). On April 29, 2014, the Supreme Court reversed the opinion of the D.C. Circuit Court and remanded the matter to the D.C. Circuit Court for further proceedings. *EPA v. EME Homer City Generation, L.P.*, No. 12–1182 (S. Ct. April 29, 2014).

In their submissions, the States do not rely on either CAIR or CSAPR for emission reductions that contributed to the Washington Area’s attainment of the 1997 annual PM_{2.5} NAAQS, nor do the States rely on either of the rules to show maintenance of the standard in the Area for 10 years following redesignation. However, because CAIR was promulgated in 2005 and incentivized sources and states to begin achieving early emission reductions, the air quality data examined by EPA in issuing a final determination of attainment for the Washington Area in 2009 (January 12, 2009, 74 FR 1146) and the air quality data from the Area since 2005 necessarily reflect reductions in emissions from upwind sources as a result of CAIR. Nonetheless, in this case EPA believes that it is appropriate to redesignate the Washington Area. Modeling conducted by EPA during the CSAPR rulemaking process, which used a baseline emissions scenario that “backed out” the effects of CAIR, *see* 76 FR at 48223, projected that the counties in the Washington Area would have PM_{2.5} annual design values¹ below the level of the 1997 annual PM_{2.5} standard for 2012 and 2014 without taking into account emissions reductions from CAIR or CSAPR. *See* Appendix B of EPA’s “Air Quality Modeling Final Rule Technical Support Document,” (Pages B–38, B–46, and B–61), which is available in the docket for this proposed rulemaking action. In addition, the 2010–2012 quality-assured, quality-controlled, and certified monitoring data for the Washington Area confirms that 2012 PM_{2.5} annual design values for each monitoring site in the Area remained well below the 1997 annual PM_{2.5} NAAQS, and thus the entire Area continued to attain the standard in

2012. *See* Table 1 of this proposed rulemaking action for the Washington Area’s monitoring data for 2010–2012.

The status of CSAPR is not relevant to these redesignations. CSAPR was promulgated in June 2011, and the rule was stayed by the D.C. Circuit Court just six months later, before the trading programs it created were scheduled to go into effect. Therefore, the Washington Area’s attainment of the 1997 annual PM_{2.5} standard cannot have been a result of any emission reductions associated with CSAPR. In sum, neither the current status of CAIR nor the current status of CSAPR affects any of the criteria for proposed approval of these redesignation requests for the Washington Area.

B. Effect of the January 4, 2013 D.C. Circuit Court Decision Regarding PM_{2.5} Implementation Under Subpart 4 of Part D of Title I of the CAA

1. Background

On January 4, 2013, in *Natural Resources Defense Council v. EPA*, the D.C. Circuit Court remanded to EPA the 1997 PM_{2.5} Implementation Rule. *Natural Resources Defense Council (NRDC) v. EPA*, 706 F.3d 428 (D.C. Cir. 2013). The D.C. Circuit Court found that EPA erred in implementing the 1997 PM_{2.5} NAAQS pursuant to the general implementation provisions of subpart 1 of Part D of Title I of the CAA (subpart 1), rather than the particulate-matter-specific provisions of subpart 4 of Part D of Title I (subpart 4).

Prior to the January 4, 2013 decision, states had worked towards meeting the air quality goals of the 1997 annual PM_{2.5} NAAQS in accordance with EPA regulations and guidance derived from subpart 1. Subsequent to this decision, in rulemaking that responds to the D.C. Circuit Court’s remand, EPA took this history into account by proposing to set a new deadline for any remaining submissions that may be required for moderate nonattainment areas as a result of the Court’s decision regarding subpart 4. On June 2, 2014 (79 FR 31566), EPA finalized the “Identification of Nonattainment Classification and Deadlines for Submission of SIP Provisions for the 1997 PM_{2.5} NAAQS and 2006 PM_{2.5} NAAQS” rule (the PM_{2.5} Subpart 4 Classification and Deadline Rule). The rule identifies the classification under subpart 4 for areas currently designated nonattainment for the 1997 annual and/or 2006 24-hour PM_{2.5} standards and sets a new deadline for states to submit attainment-related and other SIP elements required for these areas pursuant to subpart 4. The rule also

identifies EPA guidance that is currently available regarding subpart 4 requirements. The PM_{2.5} Subpart 4 Classification and Deadline Rule specifies December 31, 2014 as the deadline for the states to submit any additional attainment-related SIP elements that may be needed to meet the applicable requirements of subpart 4 for areas currently designated nonattainment for the 1997 annual and/or 2006 24-hour PM_{2.5} NAAQS and to submit SIPs addressing the nonattainment NSR requirements in subpart 4. Therefore, as explained in detail in the following section, any additional attainment-related SIP elements that may be needed for the Washington Area to meet the applicable requirements of subpart 4 were not due at the time that the District, Maryland, and Virginia submitted their redesignation requests for the Washington Area. The District, Maryland, and Virginia submitted their requests for redesignating the Washington Area for the 1997 annual PM_{2.5} NAAQS on June 3, 2013, July 10, 2013, and June 3, 2013 respectively.

2. Proposal on This Issue

EPA has considered the effect of the D.C. Circuit Court’s January 4, 2013 ruling and the PM_{2.5} Subpart 4 Nonattainment Classification and Deadline Rule on the Washington Area’s redesignation requests. In this proposed rulemaking action, EPA is proposing to determine that the D.C. Circuit Court’s January 4, 2013 decision does not prevent EPA from redesignating the Washington Area to attainment. Even in light of the D.C. Circuit Court’s decision, redesignation for the Area is appropriate under the CAA and EPA’s longstanding interpretations of the CAA provisions regarding redesignation. EPA first explains its longstanding interpretation that requirements that are imposed, or that become due, after a complete redesignation request is submitted for an area that is attaining the standard, are not applicable for purposes of evaluating a redesignation request. Second, EPA then shows that, even if EPA applies the subpart 4 requirements to the Washington Area redesignation requests and disregards the provisions of its 1997 annual PM_{2.5} implementation rule recently remanded by the D.C. Circuit Court, the States’ requests for redesignation of the Area still qualify for approval. EPA’s discussion takes into account the effect of the D.C. Circuit Court’s ruling and the proposed PM_{2.5} Subpart 4 Classification and Deadline Rule on the Area’s maintenance plan, which EPA views as approvable when subpart 4 requirements are considered.

¹ As defined in 40 CFR part 50, Appendix N, section (1)(c). A monitoring site’s design value is compared to the level of the 1997 annual PM_{2.5} NAAQS to determine compliance with the standard.

a. Applicable Requirements Under Subpart 4 for Purposes of Evaluating the Washington Area's Redesignation Requests

With respect to the 1997 PM_{2.5} Implementation Rule, the D.C. Circuit Court's January 4, 2013 ruling rejected EPA's reasons for implementing the PM_{2.5} NAAQS solely in accordance with the provisions of subpart 1, and remanded that matter to EPA, so that it could address implementation of the 1997 annual PM_{2.5} NAAQS under subpart 4, in addition to subpart 1. For the purposes of evaluating the States' redesignation requests for the Washington Area, to the extent that implementation under subpart 4 would impose additional requirements for areas designated nonattainment, EPA believes that those requirements are not "applicable" for the purposes of CAA section 107(d)(3)(E), and thus EPA is not required to consider subpart 4 requirements with respect to the redesignation of the Washington Area. Under its longstanding interpretation of the CAA, EPA has interpreted section 107(d)(3)(E) to mean, as a threshold matter, that the part D provisions which are "applicable" and which must be approved in order for EPA to redesignate an area include only those which came due prior to a state's submittal of a complete redesignation request. See 1992 Calcagni Memorandum. See also "State Implementation Plan (SIP) Requirements for Areas Submitting Requests for Redesignation to Attainment of the Ozone and Carbon Monoxide (CO) National Ambient Air Quality Standards (NAAQS) on or after November 15, 1992," Memorandum from Michael Shapiro, Acting Assistant Administrator, Air and Radiation, September 17, 1993 (Shapiro memorandum); Final Redesignation of Detroit-Ann Arbor, (60 FR 12459, 12465–66, March 7, 1995); Final Redesignation of St. Louis, Missouri, (68 FR 25418, 25424–27, May 12, 2003); *Sierra Club v. EPA*, 375 F.3d 537, 541 (7th Cir. 2004) (upholding EPA's redesignation rulemaking applying this interpretation and expressly rejecting Sierra Club's view that the meaning of "applicable" under the statute is "whatever should have been in the plan at the time of attainment rather than whatever actually was in the plan and already implemented or due at the time of attainment").² In this case, at the time

that States submitted their redesignation requests, the requirements under subpart 4 were not due.

EPA's view that, for purposes of evaluating the redesignation of the Washington Area, the subpart 4 requirements were not due at the time the States submitted the redesignation requests is in keeping with the EPA's interpretation of subpart 2 requirements for subpart 1 ozone areas redesignated subsequent to the D.C. Circuit Court's decision in *South Coast Air Quality Mgmt. Dist. v. EPA*, 472 F.3d 882 (D.C. Cir. 2006). In *South Coast*, the D.C. Circuit Court found that EPA was not permitted to implement the 1997 8-hour ozone standard solely under subpart 1, and held that EPA was required under the statute to implement the standard under the ozone-specific requirements of subpart 2 as well. Subsequent to the *South Coast* decision, in evaluating and acting upon redesignation requests for the 1997 8-hour ozone standard that were submitted to EPA for areas under subpart 1, EPA applied its longstanding interpretation of the CAA that "applicable requirements," for purposes of evaluating a redesignation, are those that had been due at the time the redesignation request was submitted. See, e.g., Proposed Redesignation of Manitowoc County and Door County Nonattainment Areas (75 FR 22047, 22050, April 27, 2010). In those actions, EPA therefore did not consider subpart 2 requirements to be "applicable" for the purposes of evaluating whether the area should be redesignated under section 107(d)(3)(E).

EPA's interpretation derives from the provisions of section 107(d)(3). Section 107(d)(3)(E)(v) states that, for an area to be redesignated, a state must meet "all requirements 'applicable' to the area under section 110 and part D." Section 107(d)(3)(E)(ii) provides that the EPA must have fully approved the "applicable" SIP for the area seeking redesignation. These two sections read together support EPA's interpretation of "applicable" as only those requirements that came due prior to submission of a complete redesignation request. First, holding states to an ongoing obligation to adopt new CAA requirements that arose after the state submitted its redesignation request, in order to be redesignated, would make it problematic or impossible for EPA to act on redesignation requests in accordance with the 18-month deadline Congress set for EPA action in section 107(d)(3)(D). If "applicable requirements" were interpreted to be a

a prerequisite to redesignation. Section 175A(c) of the CAA.

continuing flow of requirements with no reasonable limitation, states, after submitting a redesignation request, would be forced continuously to make additional SIP submissions that in turn would require EPA to undertake further notice-and-comment rulemaking actions to act on those submissions. This would create a regime of unceasing rulemaking that would delay action on the redesignation request beyond the 18-month timeframe provided by the CAA for this purpose.

Second, a fundamental premise for redesignating a nonattainment area to attainment is that the area has attained the relevant NAAQS due to emission reductions from existing controls. Thus, an area for which a redesignation request has been submitted would have already attained the NAAQS as a result of satisfying statutory requirements that came due prior to the submission of the request. Absent a showing that unadopted and unimplemented requirements are necessary for future maintenance, it is reasonable to view the requirements applicable for purposes of evaluating the redesignation request as including only those SIP requirements that have already come due. These are the requirements that led to attainment of the NAAQS. To require, for redesignation approval, that a state also satisfy additional SIP requirements coming due after the state submits its complete redesignation request, and while EPA is reviewing it, would compel the state to do more than is necessary to attain the NAAQS, without a showing that the additional requirements are necessary for maintenance.

In the context of this redesignation, the timing and nature of the D.C. Circuit Court's January 4, 2013 decision in *NRDC v. EPA* and EPA's PM_{2.5} Subpart 4 Nonattainment Classification and Deadline Rule compound the consequences of imposing requirements that come due after the redesignation requests are submitted. The States submitted their redesignation requests for the 1997 annual PM_{2.5} NAAQS on June 3, 2013 and July 10, 2013, which is prior to the deadline by which the Washington Area is required to meet the applicable requirements pursuant to subpart 4.

To require the States' fully-completed and pending redesignation requests for the 1997 annual PM_{2.5} NAAQS to comply now with requirements of subpart 4 that the D.C. Circuit Court announced only in January 2013 and for which the deadline to comply has not yet come, would be to give retroactive effect to such requirements and provide the States a unique and earlier deadline

² Applicable requirements of the CAA that come due subsequent to the area's submittal of a complete redesignation request remain applicable until a redesignation is approved, but are not required as

for compliance solely on the basis of submitting their respective redesignation requests for the Washington Area. The D.C. Circuit Court recognized the inequity of this type of retroactive impact in *Sierra Club v. Whitman*, 285 F.3d 63 (D.C. Cir. 2002),³ where it upheld the D.C. Circuit Court's ruling refusing to make retroactive EPA's determination that the St. Louis area did not meet its attainment deadline. In that case, petitioners urged the D.C. Circuit Court to make EPA's nonattainment determination effective as of the date that the statute required, rather than the later date on which EPA actually made the determination. The D.C. Circuit Court rejected this view, stating that applying it "would likely impose large costs on States, which would face fines and suits for not implementing air pollution prevention plans . . . even though they were not on notice at the time." *Id.* at 68. Similarly, it would be unreasonable to penalize the States by rejecting their redesignation request for an area that is already attaining the 1997 annual PM_{2.5} standard and that met all applicable requirements known to be in effect at the time of the requests. For EPA now to reject the redesignation requests solely because the States did not expressly address subpart 4 requirements which have not yet come due, would inflict the same unfairness condemned by the D.C. Circuit Court in *Sierra Club v. Whitman*.

b. Subpart 4 Requirements and Washington Area's Redesignation Request

Even if EPA were to take the view that the D.C. Circuit Court's January 4, 2013 decision requires that, in the context of pending redesignations for the 1997 annual PM_{2.5} standard, subpart 4 requirements were due and in effect at the time the States submitted their redesignation requests, EPA proposes to determine that the Washington Area still qualifies for redesignation to attainment for the 1997 annual PM_{2.5} standard. As explained subsequently, EPA believes that the redesignation requests for the Washington Area, though not expressed in terms of subpart 4 requirements, substantively meets the requirements of that subpart

for purposes of redesignating the Area to attainment.

With respect to evaluating the relevant substantive requirements of subpart 4 for purposes of redesignating the Washington Area, EPA notes that subpart 4 incorporates components of subpart 1, which contains general air quality planning requirements for areas designated as nonattainment. *See* section 172(c). Subpart 4 itself contains specific planning and scheduling requirements for coarse particulate matter (PM₁₀)⁴ nonattainment areas, and under the D.C. Circuit Court's January 4, 2013 decision in *NRDC v. EPA*, these same statutory requirements also apply for PM_{2.5} nonattainment areas. EPA has longstanding general guidance that interprets the 1990 amendments to the CAA, making recommendations to states for meeting the statutory requirements for SIPs for nonattainment areas. *See* the General Preamble. In the General Preamble, EPA discussed the relationship of subpart 1 and subpart 4 SIP requirements, and pointed out that subpart 1 requirements were to an extent "subsumed by, or integrally related to, the more specific PM₁₀ requirements" (57 FR 13538, April 16, 1992). The subpart 1 requirements include, among other things, provisions for attainment demonstrations, RACM, RFP, emissions inventories, and contingency measures.

For the purposes of these redesignation requests, in order to identify any additional requirements which would apply under subpart 4, consistent with EPA's April 25, 2014 PM_{2.5} Subpart 4 Nonattainment Classification and Deadline Rule, EPA is considering the Washington Area to be a "moderate" PM_{2.5} nonattainment area. As EPA explained in its April 25, 2014 rule, section 188 of the CAA provides that all areas designated nonattainment areas under subpart 4 are initially classified by operation of law as "moderate" nonattainment areas, and will remain moderate nonattainment areas unless and until EPA reclassifies the area as a "serious" nonattainment area. Accordingly, EPA believes that it is appropriate to limit the evaluation of the potential impact of subpart 4 requirements to those that would be applicable to moderate nonattainment areas. Sections 189(a) and (c) of subpart 4 apply to moderate nonattainment areas and include the following: (1) An approved permit program for construction of new and modified major stationary sources (section 189(a)(1)(A)); (2) an attainment demonstration (section

189(a)(1)(B)); (3) provisions for RACM (section 189(a)(1)(C)); and (4) quantitative milestones demonstrating RFP toward attainment by the applicable attainment date (section 189(c)).

The permit requirements of subpart 4, as contained in section 189(a)(1)(A), refer to and apply the subpart 1 permit provisions requirements of sections 172 and 173 to PM₁₀, without adding to them. Consequently, EPA believes that section 189(a)(1)(A) does not itself impose for redesignation purposes any additional requirements for moderate areas beyond those contained in subpart 1.⁵ In any event, in the context of redesignation, EPA has long relied on the interpretation that a fully approved nonattainment NSR program is not considered an applicable requirement for redesignation, provided the area can maintain the standard with a prevention of significant deterioration (PSD) program after redesignation. A detailed rationale for this view is described in a memorandum from Mary Nichols, Assistant Administrator for Air and Radiation, dated October 14, 1994, entitled, "Part D New Source Review Requirements for Areas Requesting Redesignation to Attainment." *See also* rulemakings for Detroit, Michigan (60 FR 12467–12468, March 7, 1995); Cleveland-Akron-Lorain, Ohio (61 FR 20458, 20469–20470, May 7, 1996); Louisville, Kentucky (66 FR 53665, October 23, 2001); and Grand Rapids, Michigan (61 FR 31834–31837, June 21, 1996).

With respect to the specific attainment planning requirements under subpart 4,⁶ when EPA evaluates a redesignation request under either subpart 1 or 4, any area that is attaining the PM_{2.5} standards is viewed as having satisfied the attainment planning requirements for these subparts.

For redesignations, EPA has for many years interpreted attainment-linked requirements as not applicable for areas attaining the standard. In the General Preamble, EPA stated that, "The requirements for RFP will not apply in evaluating a request for redesignation to attainment since, at a minimum, the air quality data for the area must show that the area has already attained. Showing that the State will make RFP towards attainment will, therefore, have no meaning at that point."

The General Preamble also explained that, "[t]he section 172(c)(9)

³ *Sierra Club v. Whitman* was discussed and distinguished in a recent D.C. Circuit Court decision that addressed retroactivity in a quite different context, where, unlike the situation here, EPA sought to give its regulations retroactive effect. *National Petrochemical and Refiners Ass'n v. EPA*, 630 F.3d 145, 163 (D.C. Cir. 2010), rehearing denied 643 F.3d 958 (D.C. Cir. 2011), cert denied 132 S. Ct. 571 (2011).

⁴ PM₁₀ refers to particulates nominally 10 micrometers in diameter or smaller.

⁵ The potential effect of section 189(e) on section 189(a)(1)(A) for purposes of evaluating these redesignation requests is discussed in this rulemaking action.

⁶ I.e., attainment demonstration, RFP, RACM, milestone requirements, contingency measures.

requirements are directed at ensuring RFP and attainment by the applicable date. These requirements no longer apply when an area has attained the standard and is eligible for redesignation. Furthermore, section 175A for maintenance plans . . . provides specific requirements for contingency measures that effectively supersede the requirements of section 172(c)(9) for these areas.” *Id.* EPA similarly stated in its 1992 Calcagni Memorandum that, “The requirements for reasonable further progress and other measures needed for attainment will not apply for redesignations because they only have meaning for areas not attaining the standard.”

It is evident that even if we were to consider the D.C. Circuit Court’s January 4, 2013 decision in *NRDC v. EPA* to mean that attainment-related requirements specific to subpart 4 should be imposed retroactively⁷ or prior to December 31, 2014 and, thus, were due prior to the States’ redesignation requests, those requirements do not apply to an area that is attaining the 1997 annual PM_{2.5} NAAQS, for the purpose of evaluating a pending request to redesignate the area to attainment. EPA has consistently enunciated this interpretation of applicable requirements under section 107(d)(3)(E) since the General Preamble was published more than twenty years ago. Courts have recognized the scope of EPA’s authority to interpret “applicable requirements” in the redesignation context. See *Sierra Club v. EPA*, 375 F.3d 537 (7th Cir. 2004).

Moreover, even outside the context of redesignations, EPA has viewed the obligations to submit attainment-related SIP planning requirements of subpart 4 as inapplicable for areas that EPA determines are attaining the 1997 annual PM_{2.5} standard. EPA’s prior “Clean Data Policy” rulemakings for the PM₁₀ NAAQS, also governed by the requirements of subpart 4, explain EPA’s reasoning. They describe the effects of a determination of attainment on the attainment-related SIP planning requirements of subpart 4. See “Determination of Attainment for Coso Junction Nonattainment Area,” (75 FR 27944, May 19, 2010). See also *Coso Junction Proposed PM₁₀ Redesignation*, (75 FR 36023, 36027, June 24, 2010); *Proposed and Final Determinations of Attainment for San Joaquin Nonattainment Area* (71 FR 40952, 40954–55, July 19, 2006 and 71 FR

63641, 63643–47, October 30, 2006). In short, EPA in this context has also long concluded that to require states to meet superfluous SIP planning requirements is not necessary and not required by the CAA, so long as those areas continue to attain the relevant NAAQS.

Elsewhere in this notice, EPA proposes to determine that the Washington Area has attained and continues to attain the 1997 annual PM_{2.5} NAAQS. Under its longstanding interpretation, EPA is proposing to determine here that the Washington Area meets the attainment-related plan requirements of subparts 1 and 4 for the 1997 annual PM_{2.5} NAAQS. Thus, EPA is proposing to conclude that the requirements to submit an attainment demonstration under 189(a)(1)(B), a RACM determination under section 172(c)(1) and section 189(a)(1)(c), a RFP demonstration under 189(c)(1), and contingency measure requirements under section 172(c)(9) are satisfied for purposes of evaluating these redesignation requests.

c. Subpart 4 and Control of PM_{2.5} Precursors

The D.C. Circuit Court in *NRDC v. EPA* remanded to EPA the two rules at issue in the case with instructions to EPA to re-promulgate them consistent with the requirements of subpart 4. EPA in this section addresses the D.C. Circuit Court’s opinion with respect to PM_{2.5} precursors. While past implementation of subpart 4 for PM₁₀ has allowed for control of PM₁₀ precursors such as NO_x from major stationary, mobile, and area sources in order to attain the standard as expeditiously as practicable, section 189(e) of the CAA specifically provides that control requirements for major stationary sources of direct PM₁₀ shall also apply to PM₁₀ precursors from those sources, except where EPA determines that major stationary sources of such precursors “do not contribute significantly to PM₁₀ levels which exceed the standard in the area.”

EPA’s 1997 PM_{2.5} Implementation Rule, remanded by the D.C. Circuit Court, contained rebuttable presumptions concerning certain PM_{2.5} precursors applicable to attainment plans and control measures related to those plans. Specifically, in 40 CFR 51.1002, EPA provided, among other things, that a state was “not required to address VOC [and ammonia] as . . . PM_{2.5} attainment plan precursor[s] and to evaluate sources of VOC [and ammonia] emissions in the State for control measures.” EPA intended these to be rebuttable presumptions. EPA established these presumptions at the time because of uncertainties regarding

the emission inventories for these pollutants and the effectiveness of specific control measures in various regions of the country in reducing PM_{2.5} concentrations. EPA also left open the possibility for such regulation of VOC and ammonia in specific areas where that was necessary.

The D.C. Circuit Court in its January 4, 2013 decision made reference to both section 189(e) and 40 CFR 51.1002, and stated that, “In light of our disposition, we need not address the petitioners’ challenge to the presumptions in [40 CFR 51.1002] that volatile organic compounds and ammonia are not PM_{2.5} precursors, as subpart 4 expressly governs precursor presumptions.” *NRDC v. EPA*, at 27, n.10. Elsewhere in the D.C. Circuit Court’s opinion, however, the D.C. Circuit Court observed “Ammonia is a precursor to fine particulate matter, making it a precursor to both PM_{2.5} and PM₁₀. For a PM₁₀ nonattainment area governed by subpart 4, a precursor is presumptively regulated. See 42 U.S.C. 7513a(e) [section 189(e)].” *Id.* at 21, n.7.

For a number of reasons, EPA believes that its proposed redesignation of the Washington Area for the 1997 annual PM_{2.5} NAAQS is consistent with the D.C. Circuit Court’s decision on this aspect of subpart 4. While the D.C. Circuit Court, citing section 189(e), stated that “for a PM₁₀ area governed by subpart 4, a precursor is ‘presumptively regulated,’” the D.C. Circuit Court expressly declined to decide the specific challenge to EPA’s 1997 PM_{2.5} Implementation Rule provisions regarding ammonia and VOC as precursors. The D.C. Circuit Court had no occasion to reach whether and how it was substantively necessary to regulate any specific precursor in a particular PM_{2.5} nonattainment area, and did not address what might be necessary for purposes of acting upon a redesignation request.

However, even if EPA takes the view that the requirements of subpart 4 were deemed applicable at the time the state submitted the redesignation request, and disregards the 1997 PM_{2.5} Implementation Rule’s rebuttable presumptions regarding ammonia and VOC as PM_{2.5} precursors, the regulatory consequence would be to consider the need for regulation of all precursors from any sources in the area to demonstrate attainment and to apply the section 189(e) provisions to major stationary sources of precursors. In the case of the Washington Area, EPA believes that doing so is consistent with proposing redesignation of the Area for the 1997 annual PM_{2.5} standard. The Washington Area has attained the 1997

⁷ As EPA has explained previously, we do not believe that the D.C. Circuit Court’s January 4, 2013 decision should be interpreted so as to impose these requirements on the states retroactively. *Sierra Club v. Whitman*, *supra*.

annual PM_{2.5} standard without any specific additional controls of VOC and ammonia emissions from any sources in the Area.

Precursors in subpart 4 are specifically regulated under the provisions of section 189(e), which requires, with important exceptions, control requirements for major stationary sources of PM₁₀ precursors.⁸ Under subpart 1 and EPA's prior implementation rule, all major stationary sources of PM_{2.5} precursors were subject to regulation, with the exception of ammonia and VOC. Thus, EPA must address here whether additional controls of ammonia and VOC from major stationary sources are required under section 189(e) of subpart 4 in order to redesignate the Washington Area for the 1997 annual PM_{2.5} NAAQS. As explained subsequently, EPA does not believe that any additional controls of ammonia and VOC are required in the context of these redesignations.

In the General Preamble, EPA discusses its approach to implementing section 189(e). *See* 57 FR 13538–13542. With regard to precursor regulation under section 189(e), the General Preamble explicitly stated that control of VOC under other CAA requirements may suffice to relieve a state from the need to adopt precursor controls under section 189(e). *See* 57 FR 13542. EPA in this rulemaking action proposes to determine that the States' SIPs have met the provisions of section 189(e) with respect to ammonia and VOC as precursors. This proposed determination is based on our findings that: (1) The Washington Area contains no major stationary sources of ammonia; and (2) existing major stationary sources of VOC are adequately controlled under other provisions of the CAA regulating the ozone NAAQS.⁹ In the alternative, EPA proposes to determine that, under the express exception provisions of section 189(e), and in the context of the redesignation of the Washington Area, which is attaining the 1997 annual PM_{2.5} standard, at present ammonia and VOC precursors from major stationary sources do not contribute significantly to levels exceeding the 1997 annual

PM_{2.5} standard in the Area. *See* 57 FR 13539–42.

EPA notes that its 1997 PM_{2.5} Implementation Rule provisions in 40 CFR 51.1002 were not directed at evaluation of PM_{2.5} precursors in the context of redesignation, but at SIP plans and control measures required to bring a nonattainment area into attainment for the 1997 annual PM_{2.5} NAAQS. By contrast, redesignation to attainment primarily requires the nonattainment area to have already attained due to permanent and enforceable emission reductions, and to demonstrate that controls in place can continue to maintain the standard. Thus, even if we regard the D.C. Circuit Court's January 4, 2013 decision as calling for "presumptive regulation" of ammonia and VOC for PM_{2.5} under the attainment planning provisions of subpart 4, those provisions in and of themselves do not require additional controls of these precursors for an area that already qualifies for redesignation. Nor does EPA believe that requiring the States to address precursors differently than they have already, would result in a substantively different outcome.

Although, as EPA has emphasized, its consideration here of precursor requirements under subpart 4 is in the context of a redesignation to attainment, EPA's existing interpretation of subpart 4 requirements with respect to precursors in attainment plans for PM₁₀ contemplates that states may develop attainment plans that regulate only those precursors that are necessary for purposes of attainment in the area in question, i.e., states may determine that only certain precursors need be regulated for attainment and control purposes.¹⁰ Courts have upheld this approach to the requirements of subpart 4 for PM₁₀.¹¹ EPA believes that application of this approach to PM_{2.5} precursors under subpart 4 is reasonable. Because the Washington Area has already attained the 1997 annual PM_{2.5} NAAQS with its current approach to regulation of PM_{2.5} precursors, EPA believes that it is reasonable to conclude in the context of this redesignation that there is no need to revisit the attainment control strategy with respect to the treatment of precursors. Even if the D.C. Circuit

Court's decision is construed to impose an obligation, in evaluating these redesignation requests, to consider additional precursors under subpart 4, it would not affect EPA's approval here of the States' requests for redesignation of the Washington Area for the 1997 annual PM_{2.5} NAAQS. In the context of a redesignation, the Area has shown that it has attained the standard. Moreover, the States have shown and EPA is proposing to determine that attainment of the 1997 annual PM_{2.5} NAAQS in the Area is due to permanent and enforceable emissions reductions on all precursors necessary to provide for continued attainment of the standard (*see* section V.A.3 of this rulemaking notice). It follows logically that no further control of additional precursors is necessary. Accordingly, EPA does not view the January 4, 2013 decision of the D.C. Circuit Court as precluding redesignation of the Washington Area to attainment for the 1997 annual PM_{2.5} NAAQS at this time. In summary, even if, prior to the date of the redesignation request submittal, the States were required to address precursors for the Washington Area under subpart 4 rather than under subpart 1, as interpreted in EPA's remanded 1997 PM_{2.5} Implementation Rule, EPA would still conclude that the Washington Area had met all applicable requirements for purposes of redesignation in accordance with section 107(d)(3)(E)(ii) and (v).

V. EPA's Analysis of the States' SIP Submittals

EPA is proposing several rulemaking actions for the Washington Area: (1) To redesignate the Area to attainment for the 1997 annual PM_{2.5} NAAQS; (2) to approve into the District, Maryland and Virginia SIPs the associated maintenance plan for the 1997 annual PM_{2.5} NAAQS; and (3) to approve the 2017 and 2025 PM_{2.5} and NO_x MVEBs for the Washington Area for transportation conformity purposes. EPA's proposed approvals of the redesignation request and maintenance plan for the 1997 annual PM_{2.5} NAAQS are based upon EPA's determination that the Area continues to attain the 1997 annual PM_{2.5} NAAQS, which EPA is proposing in this rulemaking action, and that all other redesignation criteria have been met for the Washington Area. The following is a description of how the States' submittals satisfy the requirements of sections 107(d)(3)(E) and 175A of the CAA for the 1997 annual PM_{2.5} NAAQS for the Washington Area.

⁸ Under either subpart 1 or subpart 4, for purposes of demonstrating attainment as expeditiously as practicable, a state is required to evaluate all economically and technologically feasible control measures for direct PM emissions and precursor emissions, and adopt those measures that are deemed reasonably available.

⁹ The Washington Area has reduced VOC emissions through the implementation of various control programs including VOC Reasonably Available Control Technology (RACT) regulations and various onroad and nonroad motor vehicle control programs.

¹⁰ *See, e.g.,* "Approval and Promulgation of Implementation Plans for California—San Joaquin Valley PM₁₀ Nonattainment Area; Serious Area Plan for Nonattainment of the 24-Hour and Annual PM₁₀ Standards," (69 FR 30006, May 26, 2004) (approving a PM₁₀ attainment plan that impose controls on direct PM₁₀ and NO_x emissions and did not impose controls on SO₂, VOC, or ammonia emissions).

¹¹ *See, e.g., Assoc. of Irrigated Residents v. EPA et al.*, 423 F.3d 989 (9th Cir. 2005).

*A. Requests for Redesignation*1. Attainment of the 1997 Annual PM_{2.5} NAAQS

EPA has previously determined that the Washington Area has attained the 1997 annual PM_{2.5} NAAQS. As noted earlier, on January 12, 2009 (74 FR 1146), EPA determined that the entire Washington Area had attained the 1997 annual PM_{2.5} standard, based on 2004–2006 and 2005–2007 quality-assured, quality-controlled, and certified ambient air quality monitoring data. Pursuant to 40 CFR 51.2004(c), this “clean data” determination for the Area suspended the requirements for each of the States to submit for their jurisdiction of the Washington Area an attainment demonstration and associated RACM, a RFP plan, contingency measures, and other planning SIPs related to the attainment of the 1997 annual PM_{2.5} NAAQS until the Area is redesignated

to attainment for the standard or EPA determines that the Area has again violated the standard, at which time such plans are required to be submitted. Then, on January 10, 2012 (77 FR 1411), EPA determined, pursuant to section 179(c), that the entire Washington Area had attained the 1997 annual PM_{2.5} NAAQS by its statutory attainment date of April 5, 2010. This determination was based on 2007–2009 quality-assured, quality-controlled, and certified ambient air quality monitoring data. The basis and effect of these determinations of attainment for the 1997 annual PM_{2.5} NAAQS were discussed in the proposed (73 FR 62945, October 22, 2008 and 76 FR 68378, November 4, 2011) and final rulemaking notices (74 FR 1146, January 12, 2009 and 77 FR 1411, January 10, 2012) for each action.

The States’ redesignation request submittals included the historic monitoring data for the annual PM_{2.5}

monitoring sites in the Washington Area. The historic monitoring data shows that the Washington Area has attained and continues to attain the 1997 annual PM_{2.5} NAAQS. The States assure that all PM_{2.5} monitoring data for the Washington Area has been quality-assured, quality-controlled, and certified by the States in accordance with 40 CFR 58.10. Furthermore, EPA has thoroughly reviewed the most recent ambient air quality monitoring data for PM_{2.5} in the Area, as submitted by the States and recorded in EPA’s Air Quality System (AQS). The PM_{2.5} quality-assured, quality-controlled, and state-certified 2008–2012 air quality data shows that the Washington Area continues to attain the 1997 annual PM_{2.5} NAAQS. The Area’s PM_{2.5} annual design values for the 2008–2010, 2009–2011, and 2010–2012 monitoring periods as well as preliminary data for 2013 are provided in Table 1.

TABLE 1—WASHINGTON AREA’S 2008–2012 ANNUAL DESIGN VALUES AND 2013 PRELIMINARY MONITORING DATA FOR THE 1997 ANNUAL PM_{2.5} NAAQS

Monitor site ID	Location	Annual design values			Preliminary 2013 data*
		2008–2010	2009–2011	2010–2012	
11–001–0041	Washington, DC	11.2	10.6	10.4	9.1
11–001–0042	Washington, DC	11.2	10.5	10.3	8.5
11–001–0043	Washington, DC	10.8	10.3	10.1	9.5
24–031–3001	Montgomery County, Maryland	10.3	10.2	10.5	7.7
24–033–0025	Prince George’s County, Maryland	11.5	10.8	10.8	**
24–033–0030	Prince George’s County, Maryland	10.0	10.8	10.8	8.8
24–033–8003	Prince George’s County, Maryland	9.9	9.1	8.8	8.1
51–013–0020	Arlington County, Virginia	10.8	10.1	9.9	8.7
51–059–0030	Fairfax County, Virginia	10.3	9.6	9.3	8.1
51–107–1005	Loudoun County, Virginia	10.3	9.5	9.5	8.3

Source: EPA AQS Preliminary Design Value Reports (AMP480) dated March 18, 2014, available in the docket for this rulemaking action.

Notes: * Corresponds to quality-assured, quality-controlled available monitoring data up to date for 2013. ** Monitoring site 24–033–0025 in Bladensburg, Maryland was permanently shutdown on December 30, 2011.

The Washington Area’s recent monitoring data supports EPA’s previous determinations that the Area has attained the 1997 annual PM_{2.5} NAAQS. In addition, as discussed subsequently with respect to the Washington Area’s maintenance plan, the States have committed to continue monitoring ambient PM_{2.5} concentrations in accordance with 40 CFR part 58. Thus, EPA is proposing to determine that the Washington Area continues to attain the 1997 annual PM_{2.5} NAAQS.

2. The States Have Met All Applicable Requirements Under Section 110 and Part D of the CAA and Have Fully Approved SIPs Under Section 110(k) for the Washington Area

In accordance with section 107(d)(3)(E)(v) of the CAA, the SIP for the 1997 annual PM_{2.5} standard for each

of the jurisdictions of the Washington Area must be fully approved under section 110(k) and all the requirements applicable to the Area under section 110 of the CAA (general SIP requirements) and part D of Title I of the CAA (SIP requirements for nonattainment areas) must be met.

a. Section 110 General SIP Requirements

Section 110(a)(2) of Title I of the CAA delineates the general requirements for a SIP, which include enforceable emissions limitations and other control measures, means, or techniques, provisions for the establishment and operation of appropriate devices necessary to collect data on ambient air quality, and programs to enforce the limitations. The general SIP elements and requirements set forth in section 110(a)(2) include, but are not limited to

the following: (1) A SIP submittal that has been adopted by the state after reasonable public notice and hearing; (2) provisions for establishment and operation of appropriate procedures needed to monitor ambient air quality; (3) implementation of a source permit program; provisions for the implementation of Part C requirements (PSD); (4) provisions for the implementation of Part D requirements for NSR permit programs; (5) provisions for air pollution modeling; and (6) provisions for public and local agency participation in planning and emission control rule development.

Section 110(a)(2)(D) of the CAA requires that SIPs contain certain measures to prevent sources in a state from significantly contributing to air quality problems in another state. To implement this provision for various NAAQS, EPA has required certain states

to establish programs to address transport of air pollutants in accordance with the NO_x SIP Call (63 FR 57356, October 27, 1998), amendments to the NO_x SIP Call (64 FR 26298, May 14, 1999 and 65 FR 11222, March 2, 2000), and CAIR (70 FR 25162, May 12, 2005). However, section 110(a)(2)(D) requirements for a state are not linked with a particular nonattainment area's designation and classification in that state. EPA believes that the requirements linked with a particular nonattainment area's designation and classifications are the relevant measures to evaluate in reviewing a redesignation request. The transport SIP submittal requirements, where applicable, continue to apply to a state regardless of the designation of any one particular area in the state. Thus, EPA does not believe that these requirements are applicable requirements for purposes of redesignation.

In addition, EPA believes that the other section 110(a)(2) elements not connected with nonattainment plan submissions and not linked with an area's attainment status are not applicable requirements for purposes of redesignation. The Washington Area will still be subject to these requirements after it is redesignated. EPA concludes that the section 110(a)(2) and part D requirements which are linked with a particular area's designation and classification are the relevant measures to evaluate in reviewing a redesignation request, and that section 110(a)(2) elements not linked to the area's nonattainment status are not applicable for purposes of redesignation. This approach is consistent with EPA's existing policy on applicability of conformity (i.e., for redesignations) and oxygenated fuels requirement. *See* Reading, Pennsylvania, proposed and final rulemakings (61 FR 53174, October 10, 1996), (62 FR 24826, May 7, 1997); Cleveland-Akron-Lorain, Ohio final rulemaking (61 FR 20458, May 7, 1996); and Tampa, Florida, final rulemaking (60 FR 62748, December 7, 1995). *See* also, the discussion on this issue in the Cincinnati, Ohio redesignation (65 FR at 37890, June 19, 2000), and in the Pittsburgh-Beaver Valley, Pennsylvania redesignation (66 FR at 53099, October 19, 2001).

EPA has reviewed the States' SIPs and has concluded that they all meet the general SIP requirements under section 110(a)(2) of the CAA to the extent they are applicable for purposes of redesignation. EPA has previously approved provisions of the States' SIPs addressing section 110(a)(2) requirements, including provisions

addressing PM_{2.5}. *See* (76 FR 20237, April 4, 2011 for the District; 76 FR 62635, October 11, 2011 for Virginia; and 76 FR 72624, November 25, 2011 for Maryland). These requirements are, however, statewide requirements that are not linked to the PM_{2.5} nonattainment status of the Washington Area. Therefore, EPA believes that these SIP elements are not applicable requirements for purposes of reviewing the States' redesignation requests for the 1997 annual PM_{2.5} NAAQS for the Washington Area.

b. Subpart 1 Requirements

Subpart 1 sets forth the basic nonattainment plan requirements applicable to PM_{2.5} nonattainment areas. Under section 172, states with nonattainment areas must submit plans providing for timely attainment and must meet a variety of other requirements. The General Preamble discusses the evaluation of these requirements in the context of EPA's consideration of a redesignation request. The General Preamble sets forth EPA's view of applicable requirements for purposes of evaluating redesignation requests when an area is attaining the standard. *See* (57 FR 13498, April 16, 1992).

On April 3, 2008, April 4, 2008, and April 8, 2008, Maryland, the District, and Virginia, respectively, submitted separately an attainment plan for their respective portions of the Washington Area for the 1997 annual PM_{2.5} NAAQS. As noted previously, on January 12, 2009 (74 FR 1146), EPA determined that the entire Washington Area had attained the 1997 annual PM_{2.5} standard, based on 2004–2006 and 2005–2007 quality-assured, quality-controlled, and certified ambient air quality monitoring data. Pursuant to 40 CFR 51.2004(c), upon EPA's clean data determination for the Area, the requirements for each of the States to submit for their jurisdiction of the Washington Area an attainment demonstration and associated RACM, a RFP plan, contingency measures, and other planning SIPs related to the attainment of the 1997 annual PM_{2.5} NAAQS were suspended until the Area is redesignated to attainment for the standard or EPA determines that the Area has again violated any of the standards, at which time such plans are required to be submitted. Thus, because attainment has been reached for the Area for the 1997 annual PM_{2.5} NAAQS and the Area continues to attain the standard, no additional measures are needed to provide for attainment. Therefore, the requirements of section 172(c)(1), 172(c)(2), 172(c)(6), and 172(c)(9) are no longer considered to be

applicable for purposes of redesignation of the Washington Area for this standard.

The requirement under section 172(c)(3) for each State was not suspended by EPA's clean data determination for the 1997 annual PM_{2.5} NAAQS for the Washington Area. Section 172(c)(3) of the CAA requires submission of a comprehensive, accurate, and current inventory of actual emissions. For purposes of the PM_{2.5} NAAQS, this emissions inventory should address not only direct emissions of PM_{2.5}, but also emissions of all precursors with the potential to participate in PM_{2.5} formation, i.e., SO₂, NO_x, VOC, and ammonia. In October 2012, EPA approved in separate rulemaking actions the 2002 emissions inventories submitted by the States with each of the attainment plans for the 1997 annual PM_{2.5} NAAQS to satisfy the requirements of section 172(c)(3) for the Washington Area. *See* (77 FR 60626, October 4, 2012 for Virginia; 77 FR 61513, October 10, 2012 for Maryland; and 77 FR 65630, October 30, 2012 for the District). The 2002 comprehensive emissions inventories for the 1997 annual PM_{2.5} standard submitted by the States with their respective attainment plans for the Washington Area included emissions estimates that cover the general source categories of point sources, area sources, onroad mobile sources, and nonroad mobile sources for each of the jurisdictions in the Area. The pollutants that comprise the States' 2002 emissions inventories for the Area are PM_{2.5}, NO_x, SO₂, VOC, and ammonia. An evaluation for each submittal of the States' 2002 comprehensive emissions inventories for the Washington Area is provided in the Technical Support Documents (TSDs) prepared by EPA for the separate rulemaking actions. *See* Docket ID No. EPA–R03–OAR–2010–0152 (District), EPA–R03–OAR–2010–0140 (Maryland), and EPA–R03–OAR–2010–0151 (Virginia).

Section 172(c)(4) of the CAA requires the identification and quantification of allowable emissions for major new and modified stationary sources in an area, and section 172(c)(5) requires source permits for the construction and operation of new and modified major stationary sources anywhere in the nonattainment area. EPA has determined that, since PSD requirements will apply after redesignation, areas being redesignated need not comply with the requirement that a nonattainment NSR program be approved prior to redesignation, provided that the area demonstrates maintenance of the NAAQS without

part D NSR. A more detailed rationale for this view is described in a memorandum from Mary Nichols, Assistant Administrator for Air and Radiation, dated October 14, 1994, entitled, "Part D New Source Review Requirements for Areas Requesting Redesignation to Attainment." Maryland and Virginia have SIP-approved PSD programs in place which will regulate major new and modified stationary sources of PM_{2.5} in the Washington Area. *See* (77 FR 45949, August 2, 2012, for Maryland and 79 FR 10377, February 25, 2014, for Virginia). Maryland and Virginia's PSD programs for PM_{2.5} will become effective in the Washington Area upon redesignation to attainment. The District lacks a SIP-approved PSD program; however it is subject to a Federal Implementation Plan (FIP) which incorporates EPA's PSD permitting requirements of 40 CFR 51.21 into the District's SIP. *See* 40 CFR 52.499.

Section 172(c)(7) of the CAA requires the SIP to meet the applicable provisions of section 110(a)(2). As noted previously, EPA finds the States' SIPs meet the requirements of section 110(a)(2) that are applicable for purposes of redesignation.

Section 175A requires a state seeking redesignation to attainment to submit a SIP revision to provide for the maintenance of the NAAQS in the area "for at least 10 years after the redesignation." In conjunction with the redesignation requests for the Washington Area, the States submitted a common maintenance plan to show continued attainment of the 1997 annual PM_{2.5} NAAQS in the Washington Area for at least 10 years after

redesignation, throughout 2025. The States are requesting that EPA approve this plan as a revision to each of their SIPs to meet the requirement of CAA section 175A. Once approved, the Washington Area's maintenance plan will ensure that the States SIPs meet the requirements of the CAA regarding maintenance of the 1997 annual PM_{2.5} NAAQS for the Area. EPA's analysis of the maintenance plan is provided in section V.B. of this rulemaking action.

Section 176(c) of the CAA requires states to establish criteria and procedures to ensure that Federally supported or funded projects conform to the air quality planning goals in the applicable SIP. The requirement to determine conformity applies to transportation plans, programs, and projects that are developed, funded or approved under title 23 of the United States Code (U.S.C.) and the Federal Transit Act (transportation conformity) as well as to all other Federally supported or funded projects (general conformity). State transportation conformity SIP revisions must be consistent with Federal conformity regulations relating to consultation, enforcement and enforceability which EPA promulgated pursuant to its authority under the CAA. EPA interprets the conformity SIP requirements as not applying for purposes of evaluating a redesignation request under CAA section 107(d) because state conformity rules are still required after redesignation, and Federal conformity rules apply where state rules have not been approved. *See Wall v. EPA*, 265 F. 3d 426 (6th Cir. 2001) (upholding this interpretation) and (60 FR 62748, December 7, 1995)

(discussing Tampa, Florida). Thus, for purposes of redesignating to attainment the Washington Area for the 1997 annual PM_{2.5} NAAQS, EPA determines that the States have met all the applicable SIP requirements under part D of Title I of the CAA.

c. The States Have Fully Approved Applicable SIPs Under Section 110(k) of the CAA

For purposes of redesignation to attainment for the 1997 annual PM_{2.5} NAAQS, EPA has fully approved all applicable requirements of the States SIPs for the Washington Area in accordance with section 110(k) of the CAA.

3. Permanent and Enforceable Reductions in Emissions

For redesignating a nonattainment area to attainment, section 107(d)(3)(E)(iii) requires EPA to determine that the air quality improvement in the area is due to permanent and enforceable reductions in emissions resulting from implementation of the SIP and applicable Federal air pollution control regulations and other permanent and enforceable reductions. In making this demonstration, the States have considered changes in emissions between 2002, a year showing nonattainment for the 1997 annual PM_{2.5} standard in the Washington Area, and 2007, one of the years for which the Washington Area monitored attainment for the standard. A summary of the emissions reductions for PM_{2.5}, NO_x, SO₂, VOC, and ammonia from 2002 to 2007 for the Washington Area is provided in Table 2.

TABLE 2—COMPARISON OF 2002 NONATTAINMENT YEAR AND 2007 ATTAINMENT YEAR EMISSIONS INVENTORIES FOR THE WASHINGTON AREA, IN TONS PER YEAR (TPY)

Location	Year	Emissions (tpy)				
		PM _{2.5}	SO ₂	NO _x	VOC	Ammonia
District portion	2002	1,077	3,597	15,401	15,877	407
	2007	1,691	2,156	13,148	1,508	381
	Changes	614	–1,441	–2,253	–14,369	–26
Maryland portion	2002	12,825	169,789	109,041	98,626	5,174
	2007	12,088	178,827	91,272	11,397	4,021
	Changes	–737	9,038	–17,769	–87,229	–1,153
Virginia portion	2002	8,277	49,975	75,910	92,725	2,371
	2007	6,944	10,457	60,826	12,153	1,802
	Changes	–1,333	–39,518	–15,084	–80,572	–569
Washington Area	2002	22,179	235,165	188,548	207,228	7,952
	2007	20,724	191,441	165,247	25,058	6,204
	Changes	–1,455	–43,724	–23,301	–182,170	–1,748

As explained earlier, the States submitted their 2002 emissions inventories with their respective

attainment plans for the 1997 annual PM_{2.5} NAAQS, which EPA approved in their SIPs to satisfy the requirement of

section 172(c)(3) for the Washington Area. *See* (77 FR 60626, October 4, 2012 for Virginia; 77 FR 61513, October 10,

2012 for Maryland; and 77 FR 65630, October 30, 2012 for the District). An evaluation for each submittal of the States' 2002 comprehensive emissions inventories for the Washington Area is provided in the Technical Support Documents (TSDs) prepared by EPA for the separate rulemaking actions. See Docket ID No. EPA-R03-OAR-2010-0152 (District), EPA-R03-OAR-2010-0140 (Maryland), and EPA-R03-OAR-2010-0151 (Virginia). The 2007 emissions inventories were provided as part of the States' redesignation requests and maintenance plan submittals, and then were supplemented by the States to include emissions estimates of ammonia and VOC. EPA has evaluated the 2007 emissions inventories as part of this rulemaking action. EPA's analysis of the 2007 emissions inventories is provided in the TSD dated March 17, 2014, available in the docket for this rulemaking action at www.regulations.gov.

The reduction in emissions and the corresponding improvement in air quality from 2002 to 2007 in the Washington Area can be attributed to a number of State and Federal control measures that have been implemented by the States in recent years. Point source emissions of PM_{2.5}, SO₂, and NO_x are dominated in the Washington Area by the emissions from power plants (i.e., stationary sources containing electric generating units (EGUs)). There are six power plants located in the Washington Area: (1) The Possum Point Power Station in Fairfax, Virginia; (2) the Potomac River Power Station in Alexandria, Virginia; (3) the Chalk Point Generating Plant, in Prince George's County, Maryland; (4) the Dickerson Generating Plant, in Montgomery County, Maryland; (5) the Morgantown Generating Plant, in Charles County, Maryland; and (6) the Benning Road Generating Station in the District.

Significant improvement in the Washington Area's air quality is due to permanent emissions reductions resulting from EGUs as a result of two Federal consent orders. A Federal consent decree with the Virginia Electric and Power Company (VEPCO), signed on April 17, 2003, required two boilers (units 3 and 4) in the Possum Point Power Station in Fairfax, Virginia to switch from burning coal to natural gas and to limit their combined emissions of NO_x by May 2003. The consent decree established a combined emissions limit of 219 tons of NO_x in any 365 days, rolled daily. The required control measures resulted in significant emissions reductions of NO_x and SO₂, as summarized in Table 3. This requirement was codified in a Federally enforceable permit issued by VADEQ on October 5, 2001, under the SIP-approved provisions of Article 8 and 9 of 9VAC5 Chapter 80 (Permits for Stationary Sources).

TABLE 3—REDUCTIONS OF NO_x AND SO₂ EMISSIONS FROM 2002 TO 2007 IN THE POSSUM POINT POWER STATION

Unit ID	2002 Emissions (tpy)		2007 Emissions (tpy)		Emissions reductions (%)	
	SO ₂	NO _x	SO ₂	NO _x	SO ₂	NO _x
3	6,228	1,582	0	39	100	97.53
4	10,975	2,349	1	111	99.99	95.27
Total	17,203	3,931	1	150	99.99	96.18

Additionally, in a joint Federal-State consent order, Mirant Mid-Atlantic agreed to significantly reduce emissions in four of the power plants located in

the Washington Area: Chalk Point Generating Plant, Dickerson Generating Plant, Morgantown Generating Plant, and Potomac River Generating Station.

Reductions of NO_x emissions resulting from the consent decree are summarized in Table 4.

TABLE 4—REDUCTIONS OF NO_x EMISSIONS FROM 2002 TO 2007 IN THE MIRANT MID-ATLANTIC FACILITIES IN THE WASHINGTON AREA

Facility	Unit ID	2002 NO _x Emissions		2007 NO _x Emissions		Emissions reduction
		Pounds per million British thermal units (lbs/MMBTU)	tpy	lbs/MMBTU	tpy	Percentage (%)
Chalk Point	1	0.562	6,337	0.446	4,885	22.9
	2	0.560	6,755	0.450	4,835	28.4
	3	0.156	846	0.136	538	36.4
	4	0.169	1,169	0.128	426	63.6
Dickerson	1	0.466	2,121	0.343	1,645	22.5
	2	0.498	2,444	0.334	1,644	32.7
	3	0.471	2,661	0.338	1,658	37.7
Morgantown	1	0.504	10,014	0.191	3,097	69.0
	2	0.501	8,605	0.360	6,321	26.5
Potomac River	1	0.379	759	0.326	483	36.3
	2	0.416	789	0.287	444	43.7
	3	0.418	1,545	0.254	412	73.4
	4	0.415	1,443	0.234	481	66.6
	5	0.398	1,474	0.245	516	65.0
Total			46,962		27,386	42.7

Additionally, a variety of Federal vehicle control programs have contributed to reduced onroad emissions of PM_{2.5}, NO_x, and SO₂ in the Washington Area between 2002 and 2007. EPA's Federal Tier 1 New Vehicle Emission and New Federal Evaporative Emission Standards Rule established motor vehicle emission standards, which were phased in beginning with model year 1994. *See* 40 CFR 86, subpart A. The benefits of this program are reflected in the 2002 base year and the 2007 attainment year emissions inventories. This Federally implemented program affects light duty vehicles and light duty trucks. The regulations require more stringent exhaust emission standards as well as a uniform level of evaporative emission controls.

Under the National Low Emission Vehicle Program, automobile manufacturers agreed to comply with tailpipe standards that were more stringent than EPA could mandate prior to model year 2004. *See* 40 CFR 86, subpart R. The program was in place nationwide for model year 2001, and the benefits of this program are reflected in the 2002 base year and the 2007 attainment year emissions inventories.

The Tier 2 Motor Vehicle Emission Rule was promulgated by EPA on February 10, 2000 (65 FR 6698) and requires more stringent tailpipe emissions standards for all passenger vehicles, including sport utility vehicles, minivans, vans, and pick-up trucks. This rule also requires lower levels of sulfur in gasoline, which ensured the effectiveness of low emission control technologies in vehicles and reduced harmful air pollution. The tailpipe standards required passenger vehicles to be 77 to 95 percent cleaner than those built before the rule was promulgated and the sulfur standards reduced the sulfur content of gasoline up to 90 percent by 2006. The benefits of this program are reflected in the 2007 attainment year emissions inventory.

The Heavy Duty Diesel Engine Rules are Federal rules that required truck manufacturers to comply with more stringent tailpipe standards by 2004 (65 FR 59896, October 6, 2000) and 2007 (66 FR 5002, January 18, 2001). The 2007 rule also mandated use of ultra-low sulfur diesel fuel to enable modern pollution control technology on trucks and buses. Refineries began producing the cleaner-burning diesel fuel for use in highway vehicles beginning June 1,

2006. The benefits of this program are reflected in the 2007 attainment year emissions inventory.

The States have implemented enhanced vehicle emissions inspection and maintenance (enhanced I/M) programs. *See* 64 FR 31498 (June 11, 1999) for the District; 64 FR 58340, (October 29, 1999) for Maryland; and 64 FR 47670 (September 1, 1999) for Virginia. These regional I/M programs are stricter than the basic programs, as required under sections 182 and 202 of the CAA. Enhanced I/M procedures include the use of On Board Diagnostic (OBD) system evaluations, a wider range of vehicles tested, and may include a dynamometer (treadmill) test that checks the car's emissions under driving conditions. The benefits of these I/M programs are reflected in the 2002 base year and the 2007 attainment year emissions inventories.

The reductions in emissions from the onroad sector between 2002 and 2007 are presented in Table 5. These emissions estimates were derived using the Motor Vehicle Emissions Simulator (MOVES2010a) and the most recent planning assumptions as provided by the Metropolitan Washington Council of Governments, Transportation Planning Board (MWCOTB/TBP).

TABLE 5—CHANGES IN ONROAD MOBILE EMISSIONS OF DIRECT PM_{2.5} AND PRECURSORS FROM 2002 TO 2007 IN THE WASHINGTON AREA, IN TPY

Location	Year	Emissions (tpy)				
		PM _{2.5}	SO ₂	NO _x	VOC	Ammonia
District portion	2002	156	376	8,827	4,913	383
	2007	272	68	7,512	3,362	195
	Changes	116	−308	−1315	−1551	−188
Maryland portion	2002	841	894	47,640	20,495	2,035
	2007	1,757	319	47,279	18,449	929
	Changes	916	−575	−361	−2,046	−1,106
Virginia portion	2002	727	1,562	41,108	18,496	1,827
	2007	1,422	220	36,848	15,703	777
	Changes	695	−1,342	−4,260	−2,793	−1,050
Washington Area	2002	1,725	2,833	97,575	43,904	4,246
	2007	3,452	607	91,639	37,514	1,901
	Changes	1,727	−2,226	−5,936	−2,345	−2,345

EPA believes that the States have adequately demonstrated that the observed air quality improvement in the Washington Area is due to permanent and enforceable reductions in emissions resulting from implementation of Federal and State-adopted measures.

B. Maintenance Plan

As required by section 175A of the CAA, the States submitted a common maintenance plan as a revision to their respective SIPs to ensure continued attainment of the 1997 annual PM_{2.5} standard in the Washington Area

throughout 2025. The Washington Area's maintenance plan for the 1997 annual PM_{2.5} standard was submitted to the EPA by DDOE on June 3, 2013, by MDE on July 10, 2013, and by VADEQ on June 3, 2013. As part of the maintenance demonstration the SIP revision includes a 2007 attainment emissions inventory, a 2017 interim emissions inventory, and a 2025 end year maintenance plan emissions inventory. The emissions inventories were subsequently supplemented by the States to provide for emissions estimates of VOC and ammonia as part of the

2007, 2017 and 2025 emissions inventories. The supplemental inventories were submitted to EPA on July 22, 2013 by DDOE, on July 26, 2013 by MDE, and on July 17, 2013 by VADEQ. EPA's analysis for proposing approval of the Washington Area's maintenance plan is provided in this section.

1. Attainment Emissions Inventory

An attainment inventory is comprised of the emissions during the time period associated with the monitoring data showing attainment. The States

determined that the appropriate attainment inventory year for the maintenance plan is 2007, one of the years in the period during which the Area monitored attainment of the 1997 annual PM_{2.5} NAAQS. The 2007 attainment emissions inventory contains primary PM_{2.5} emissions (including condensables), SO₂, NO_x, VOC, and ammonia for point, area, nonroad, and onroad source categories.

For the emissions estimates of the point, area, and nonroad categories of the 2007 attainment emissions inventory, the States submitted version 3 of the 2007 emissions inventory developed through the Mid-Atlantic Regional Air Management Association (MARAMA) regional process. The 2007 onroad source estimates were developed by MWCOC/TBP using EPA's MOVES 2010a model. More information on the development of the onroad emissions can be found on the States' TSD submitted as part of their redesignation request submittals.

EPA has reviewed the inventory and the documentation provided by the States and found the 2007 attainment emissions inventory submitted with the Washington Area's maintenance plan to be approvable. For more information on EPA's analysis of the 2007 emissions inventory, see EPA's TSD dated March 17, 2014, available in the docket for this rulemaking action at www.regulations.gov.

2. Maintenance Demonstration

Section 175A requires a state seeking redesignation to attainment to submit a

SIP revision to provide for the maintenance of the NAAQS in the area "for at least 10 years after the redesignation." EPA has interpreted this as a showing of maintenance "for a period of ten years following redesignation." Where the emissions inventory method of showing maintenance is used, its purpose is to show that emissions during the maintenance period will not increase over the attainment year inventory. See 1992 Calcagni Memorandum, pages 9–10.

For a demonstration of maintenance, emissions inventories are required to be projected to future dates to assess the influence of future growth and controls; however, the demonstration need not be based on modeling. See *Wall v. EPA*, *supra*; *Sierra Club v. EPA*, *supra*. See also 66 FR 53099–53100 and 68 FR 25430–32. The States use projection inventories to show that the Washington Area will remain in attainment and developed projection inventories for an interim year of 2017 and a maintenance plan end year of 2025 to show that future emissions of NO_x, SO₂, and direct PM_{2.5} will remain at or below the attainment year 2007 emissions levels throughout the Area through the year 2025.

The States used the 2017 and 2025 emissions projections developed through the MARAMA regional planning process as the 2017 interim year and the 2025 maintenance plan end year emissions inventories. For more details on emissions projections,

methodologies, and growth, see MARAMA's "Technical Support Document for the Development of the 2013/2017/2020 Emission Inventories for Regional Air Quality Modeling in the Northeast/Mid-Atlantic Region" (MARAMA 2017 TSD) and the "Technical Support Document for the Development of the 2025 Emission Inventory for PM_{2.5} Nonattainment Counties in the MANE–VU Region, January 2012" (MARAMA 2025 TSD), respectively, which were included in the States submittals and are available in the docket for this rulemaking action at www.regulations.gov. After reviewing the supporting documentation provided for developing the projected emissions inventories, EPA has determined that the 2017 and 2025 emissions inventories for the Washington Area are approvable.

A summary of the emissions inventories for the Washington Area for the 2007 attainment year, the 2017 interim year, and the 2025 maintenance plan end year is provided in Table 6. The inventories show that, between 2007 and 2025, the Area is projected to reduce SO₂ emissions by 155,071 tpy, NO_x emissions by 14,811 tpy, VOC emissions by 29,473 tpy, and ammonia emissions by 534 tpy. Thus, the emissions inventories show that the Washington Area will continue to maintain the 1997 annual PM_{2.5} standards during the maintenance period.

TABLE 6—COMPARISON OF 2007 ATTAINMENT YEAR AND 2017 AND 2025 PROJECTED EMISSIONS INVENTORIES FOR THE WASHINGTON AREA, IN TPY

Pollutants/Year	2007	2017	2025	Reductions 2007–2017	Reductions 2007–2025
PM _{2.5}	20,724	18,654	18,010	–2,070	–2,714
SO ₂	191,441	33,315	33,287	–158,125	–158,153
NO _x	165,247	90,799	74,504	–74,448	–90,743
VOC	114,235	92,592	84,762	–21,643	–29,473
Ammonia	6,204	5,922	5,670	–282	–534

Point, nonroad, and onroad emission projections for 2017 and 2025 include a variety of control strategies that will reduce emissions of PM_{2.5}, NO_x, and SO₂ in the Area. Many of these programs are Federal programs that are enforced on a regional or national level. In cases where the programs are delegated programs or State programs, the States commit to the continuation of each program to ensure that reductions assumed in 2017 and 2025 will be achieved.

As explained earlier, EGUs are the primary point sources of PM_{2.5}, SO₂, and NO_x emissions in the Washington Area. The States have implemented various Federally-enforceable measures in the Washington Area to reduce emissions from EGUs. The VEPCO Federal consent decree has reduced significantly emissions of NO_x and SO₂ at the Possum Point Power Station, in Fairfax County, Virginia. The fuel switch from coal to natural gas required by the consent decree was made in the 2003–2004 timeframe. Two other permitting

actions affected the emissions of SO₂ and NO_x from the Potomac River Power Station, in Alexandria, Virginia. The first was a state operating permit issued on July 31, 2008 by Virginia's Air Pollution Control Board limiting the facility's primary PM_{2.5} emissions to 207 tpy, the SO₂ emissions to 3,813 tpy, and the NO_x emissions to 3,700 tpy. On July 29, 2010, a second state operating permit was issued, further limiting the facility to 890 tons of NO_x per ozone season (May 1 through September 30).

The Maryland Healthy Air Act (HAA) regulations became effective on July 16, 2007 and were approved by EPA into the Maryland SIP on September 4, 2008 (73 FR 51599). The HAA requires reductions in NO_x and SO₂ emissions from large coal burning power plants in Maryland. Specifically, this program limits emissions from the Chalk Point Generating Plant, the Dickerson Generating Plant, and the Morgantown Generating Plant, all of which are coal fired power plants located within the Maryland portion of the Washington Area. Emission reductions from the HAA are phased: The first phase required reductions in the 2009–2010 timeframe and the second phase required controls by 2012–2013. At full implementation, the HAA was projected to reduce NO_x emissions by approximately 75 percent from 2002 levels and SO₂ emissions by approximately 85 percent from 2002 levels.

As a condition of an operating permit, two EGUs in the Pepco Energy Services, Inc. located within the Area permanently ceased operation by December 17, 2012. The permit condition became Federally enforceable as part of a SIP revision that was approved by EPA on February 2, 2012 (77 FR 5191). Closure of the two large, uncontrolled oil-fired turbines will result in SO₂ and NO_x reductions. Additional Federal and State measures have been implemented in the Area to reduce emissions from the mobile source sector, including: EPA's Nonroad Diesel Rule, EPA's 2007 Heavy-duty Highway Rule, EPA's Tier 1 Federal Motor Vehicle Emission Standards, EPA's Tier 2 Vehicle and Gasoline Sulfur Program, and States' enhanced vehicle emissions I/M programs.

3. Monitoring Network

The District, Maryland, and Virginia operate a PM_{2.5} air quality monitoring network in the Washington Area that is significantly more robust than required by EPA's monitoring regulations in 40 CFR part 58. Furthermore, the Washington Area's maintenance plan includes the States' commitment to continue to operate and maintain its PM_{2.5} air quality monitoring network, consistent with EPA's monitoring requirements, as necessary to demonstrate ongoing compliance with the 1997 annual PM_{2.5} NAAQS. In accordance with the requirements of 40 CFR part 58, the States will consult with EPA prior to making any necessary changes to the PM_{2.5} monitoring network in the Area and will continue to submit quality-controlled, quality-assured monitoring data.

4. Verification of Continued Attainment

The States have the legal authority to implement and enforce specified measures to attain and implement the 1997 annual PM_{2.5} NAAQS, as required by section 110(a)(2) of the CAA. The States commit to continue implementing the necessary control measures that will assure maintenance of the 1997 annual PM_{2.5} NAAQS throughout the 10 year period following redesignation. Additionally, each of the States will acquire ambient and source emission data to track attainment and maintenance. As explained subsequently, as a contingency measure the States will track progress of the maintenance demonstration by periodically evaluating the projected emission inventories, based on annual and periodic inventories. *See* section V.B.5 of this proposed rulemaking action. Furthermore, the States will prepare and submit to EPA every three years a comprehensive PM_{2.5} emissions inventory, as required by EPA's Air Emissions Reporting Requirements (AERR).

5. Contingency Measures

Section 175A of the CAA requires that a maintenance plan include such contingency measures as EPA deems necessary to ensure that the States will promptly correct a violation of the 1997 annual PM_{2.5} NAAQS that occurs in the Washington Area after redesignation. The maintenance plan should identify the events that would "trigger" the adoption and implementation of a contingency measure(s), the contingency measure(s) that would be adopted and implemented, and the schedule indicating the time frame by which the state would adopt and implement the measure(s).

The Washington Area maintenance plan outlines the procedures for the adoption and implementation of contingency measures that will further reduce emissions in the Area, should a violation of the 1997 annual PM_{2.5} NAAQS occur. The States' contingency measures will be implemented if any of the following triggering events occur: The total actual annual emissions of NO_x, SO₂ or primary PM_{2.5} exceed the levels of the 2007 attainment year emissions inventory; an exceedance of the 1997 annual PM_{2.5} standard, that is, an annual average for one year at any EPA-approved monitor in the Area of 15.0 µg/m³ or greater; or a violation of the 1997 annual PM_{2.5} standard, that is, a 3-year average of the annual average at any EPA-approved monitor in the Area of 15.0 µg/m³ or greater.

Should actual emissions inventory data for any future year of the maintenance period indicate that the Washington Area's total emissions of NO_x, SO₂, or primary PM_{2.5} exceed the levels of the Area's 2007 attainment emissions inventory, the States would commence an audit to determine whether inventory refinements are needed. This audit may include, but would not be limited to, a determination that the appropriate models, control strategies, monitoring strategies, planning assumptions, industrial throughput, and production data were used in the emissions estimates for both the 2007 attainment year and the future year in question. The results of this audit will be provided to EPA. If the States find that this audit does not reconcile the estimated emissions exceedances, then each of the States commit to implement one or more of the contingency measures, as necessary so that the future actual emissions estimates for the Washington Area do not continue to exceed the levels of the 2007 attainment emissions inventory.

Additionally, if an annual exceedance of the standard occurs in the Area, each of the States commit to implementing one of the contingency measures, as described subsequently, which apply to their individual jurisdictions, to garner additional emission reductions for air quality improvement. If a violation of the standard occurs in the Area, each of the States commit to implementing two or more of the contingency measures. The States' contingency measures consist of the following state regulations or control programs: PM_{2.5} RACM determination, NO_x RACM determination, SO₂ RACM determination (for the District and Virginia portions of the Area), nonroad diesel emission reduction strategies, low sulfur home heating oil requirements (for the District and Maryland portions of the Area), alternative fuel and diesel retrofit programs for fleet vehicle operations, and wet suppression upgrade requirements in concrete manufacturing. If a RACM determination is selected as a contingency measure and the analysis shows that no control measures are economically and technically feasible, then the State would consider an alternative contingency measure from the options listed.

The States commit to a schedule for adoption and implementation of any contingency measure following three months from when an exceedance or violation of the 1997 annual PM_{2.5} standard is determined, based on the air quality assured data; or an exceedance of actual emissions from the levels of

the 2007 attainment emissions inventory is determined, as concluded by an audit. After this 3-month period, the selected contingency measure must be adopted by the State within six months, and implemented within six months of adoption. Compliance with the regulation, or full program implementation, must be achieved within 12 months of adoption.

C. Transportation Conformity Determinations

Section 176(c) of the CAA requires Federal actions in nonattainment and maintenance areas to “conform to” the goals of SIPs. This means that such actions will not cause or contribute to violations of a NAAQS, worsen the severity of an existing violation, or delay timely attainment of any NAAQS or any interim milestone. Actions involving Federal Highway Administration (FHWA) or Federal Transit Administration (FTA) funding or approval are subject to the transportation conformity rule (40 CFR Part 93, subpart A). Under this rule, metropolitan planning organizations (MPOs) in nonattainment and maintenance areas coordinate with state air quality and transportation agencies, EPA, and the FHWA and FTA to demonstrate that their long range transportation plans and transportation improvement programs (TIP) conform to

applicable SIPs. This is typically determined by showing that estimated emissions from existing and planned highway and transit systems are less than or equal to the MVEBs contained in the SIP.

The Washington Area’s maintenance plan includes MVEBs for PM_{2.5} and NO_x for the 1997 annual PM_{2.5} NAAQS. The MVEBs were submitted for the years 2017 and 2025 for the 1997 PM_{2.5} NAAQS, consistent with the emissions inventories in the Washington Area. The combined maintenance plan did not provide emission budgets for SO₂, VOC, and ammonia because it concluded, consistent with the presumptions regarding these precursors in the Transportation Conformity Rule at 40 CFR 93.102(b)(2)(v), which predated and was not disturbed by the litigation on the 1997 PM_{2.5} Implementation Rule, that emissions of these precursors from motor vehicles are not significant contributors to the Area’s PM_{2.5} air quality problem. EPA issued conformity regulations to implement the 1997 annual PM_{2.5} NAAQS in July 2004 and May 2005 (69 FR 40004, July 1, 2004 and 70 FR 24280, May 6, 2005). Those actions were not part of the final rule recently remanded to EPA by the D.C. Circuit Court in *NRDC v. EPA*, No. 08–1250 (January 4, 2013), in which the D.C. Circuit Court remanded to EPA the 1997 PM_{2.5} Implementation Rule

because it concluded that EPA must implement that NAAQS pursuant to the PM-specific implementation provisions of subpart 4, rather than solely under the general provisions of subpart 1. That decision does not affect EPA’s proposed approval of the MVEBs for the Washington Area.

The Washington Area maintenance plan includes a tiered approach for MVEBs to be applied to all future transportation conformity determinations and analyses for the 1997 annual PM_{2.5} NAAQS. Shown in Table 7 and Table 8 are the MVEBs from the Washington Area maintenance plan. The Tier 1 MVEBs shown in Table 7 will be the applicable MVEBs after the adequacy findings are effective. The Tier 2 MVEBs shown in Table 8 adds a twenty percent (20%) transportation buffer to the mobile emissions inventory projections for PM_{2.5} and NO_x in 2017 and 2025. The Tier 2 MVEBs will become effective if it is determined that technical uncertainties primarily due to model changes and to vehicle fleet turnover, which may affect future motor vehicle emissions inventories, lead to motor vehicle emissions estimates above the Tier 1 MVEBs. This determination will be made through the interagency consultation process and fully documented within the first conformity analysis that uses the Tier 2 MVEBs.

TABLE 7—TIER 1 ON-ROAD MVEBs FOR THE WASHINGTON AREA FOR THE 1997 PM_{2.5} NAAQS

Year	MVEB for PM _{2.5} on-road emissions (tpy)	MVEB for NO _x on-road emissions (tpy)
2017	1,787	41,709
2025	1,350	27,400

TABLE 8—TIER 2 ON-ROAD MVEBs FOR THE WASHINGTON AREA FOR THE 1997 PM_{2.5} NAAQS

Year	MVEB for PM _{2.5} on-road emissions (tpy)	MVEB for NO _x on-road Emissions (tpy)
2017	2,144	50,051
2025	1,586	32,880

EPA’s substantive criteria for determining adequacy of MVEBs are set out in 40 CFR 93.118(e)(4). Additionally, to approve the MVEBs, EPA must complete a thorough review of the SIP revision, in this case the Washington Area maintenance plan, and conclude that with the projected level of motor vehicle and all other emissions, the SIP revision will achieve its overall purpose, in this case providing for maintenance of the 1997 annual PM_{2.5} NAAQS. EPA’s process for determining adequacy of a MVEB consists of three basic steps: (1)

Providing public notification of a SIP submission; (2) providing the public the opportunity to comment on the MVEB during a public comment period; and (3) EPA taking action on the MVEB.

On February 5, 2013, EPA initiated an adequacy review of the MVEBs for the 1997 annual PM_{2.5} NAAQS that the Maryland, Virginia, and the District included in their maintenance plan submittals. As such, separate notices of the submission of these MVEBs were posted on the adequacy Web site (<http://epa.gov/otaq/stateresources/transconf/cursips.htm>). The public comment

period closed on March 7, 2014. There were no public comments received. EPA is acting on making these adequacy findings final through separate notices of adequacy. EPA has reviewed the MVEBs and found them consistent with the redesignation requests and maintenance plans and that the budgets meet the criteria for adequacy and approval. Therefore, EPA is proposing to approve the 2017 and 2025 PM_{2.5} and NO_x MVEBs for the Washington Area for transportation conformity purposes. Additional information pertaining to the review of the MVEBs can be found in

EPA's TSD dated February 11, 2014, available on line at www.regulations.gov, Docket ID No. EPA-R03-OAR-2014-0148.

VI. General Information Pertaining to SIP Submittals From the Commonwealth of Virginia

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) "privilege" for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1-1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information that: (1) Are generated or developed before the commencement of a voluntary environmental assessment; (2) are prepared independently of the assessment process; (3) demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) are required by law.

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege law, Va. Code Sec. 10.1-1198, precludes granting a privilege to documents and information "required by law," including documents and information "required by Federal law to maintain program delegation, authorization or approval," since Virginia must "enforce Federally authorized environmental programs in a manner that is no less stringent than their Federal counterparts. . . ." The opinion concludes that "[r]egarding § 10.1-1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by

Federal law to maintain program delegation, authorization or approval."

Virginia's Immunity law, Va. Code Sec. 10.1-1199, provides that "[t]o the extent consistent with requirements imposed by Federal law," any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any Federally authorized programs, since "no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with Federal law, which is one of the criteria for immunity."

Therefore, EPA has determined that Virginia's Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its program consistent with the Federal requirements. In any event, because EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on Federal enforcement authorities, EPA may at any time invoke its authority under the CAA, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the CAA is likewise unaffected by this, or any, state audit privilege or immunity law.

VII. Proposed Actions

EPA is proposing to approve the requests submitted by the District of Columbia, the Commonwealth of Virginia, and the State of Maryland to redesignate from nonattainment to attainment their respective portions of the Washington Area for the 1997 annual PM_{2.5} NAAQS. EPA has evaluated the States' redesignation requests and determined that they meet the redesignation criteria set forth in section 107(d)(3)(E) of the CAA for the 1997 annual PM_{2.5} standard. EPA believes that the monitoring data demonstrate that the Washington Area is attaining and will continue to attain the 1997 annual PM_{2.5} NAAQS. EPA is also proposing to approve the common maintenance plan for the Washington Area submitted by the States as revisions to their respective SIPs for the 1997 annual PM_{2.5} standard because the plan meets the requirements of CAA section 175A for the standard.

Furthermore, EPA is proposing to approve the 2017 and 2025 PM_{2.5} and NO_x MVEBs submitted by the Washington Area for transportation conformity purposes. Final approval of the redesignation requests would change the official designations of the Washington Area, from nonattainment to attainment as found at 40 CFR part 81, for each of the States for the 1997 annual PM_{2.5} NAAQS, and would incorporate into the States SIPs the maintenance plan ensuring continued attainment of the 1997 annual PM_{2.5} NAAQS in the Area for the next 10 years, until 2025. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

VIII. Statutory and Executive Order Reviews

Under the CAA, redesignation of an area to attainment and the accompanying approval of the maintenance plan under CAA section 107(d)(3)(E) are actions that affect the status of geographical area and do not impose any additional regulatory requirements on sources beyond those required by state law. A redesignation to attainment does not in and of itself impose any new requirements, but rather results in the application of requirements contained in the CAA for areas that have been redesignated to attainment. Moreover, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law and the CAA. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described

in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rulemaking action, in which EPA is proposing approval of the redesignation requests and maintenance plan submitted by the District of Columbia, the Commonwealth of Virginia, and the State of Maryland for the 1997 annual PM_{2.5} Washington Area, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Nitrogen oxides, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

40 CFR Part 81

Air pollution control, National parks, Wilderness areas.

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

Dated: July 17, 2014.

William C. Early,

Deputy Regional Administrator, Region III.

[FR Doc. 2014–18482 Filed 8–5–14; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 2, and 27

[GN Docket No. 13–185; Report No. 3005]

Petitions for Reconsideration of Action in Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petition for reconsideration.

SUMMARY: Petitions for Reconsideration (Petitions) have been filed in the Commission's Rulemaking proceeding by Jim Kirkland, on behalf of Trimble Navigation Limited, and Catherine Wang, on behalf of Deer & Company (jointly filed) and by Dane E. Erickson, on behalf Engineers for the Integrity of Broadcast Auxiliary Services Spectrum.

DATES: Oppositions to the Petitions must be filed by August 21, 2014. Replies to an opposition must be filed by September 2, 2014.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: For additional information on this proceeding, contact Ronald Repasi, Office of Engineering and Technology, at (202) 418–0768 or ronald.repasi@fcc.gov, or Peter Daronco, Broadband Division, Wireless Telecommunications Bureau, at (202) 418–7235 or peter.daronco@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of Commission's document, Report No. 3005, released July 17, 2014. The full text of this document is available for viewing and copying in Room CY–B402, 445 12th Street SW., Washington, DC or may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc. (BCPI) (1–800–378–3160). The Commission will not send a copy of this *Notice* pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A), because this *Notice* does not have an impact on any rules of particular applicability.

Subject: Amendment of the Commission's Rules with Regard to Commercial Operations in the 1695–1710 MHz, 1755–1780 MHz, and 2155–2180 MHz Bands, GN Docket No. 13–185, Report and Order, FCC 14–31, published at 79 FR 32366, June 4, 2014. Published pursuant to 47 CFR 1.429(e). See also 47 CFR 1.4(b)(1) of the Commission's rules.

Number of Petitions Filed: 2

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2014–18527 Filed 8–5–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 2, 90, 95, and 96

[GN Docket No. 12–354; FCC 14–49; DA 14–1071]

Commission Seeks Comment on Shared Commercial Operations in the 3550–3650 MHz Band; Extension of Reply Comment Period

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension of reply comment period.

SUMMARY: In this document the Federal Communications Commission extends the deadline for filing reply comments on its *Further Notice of Proposed Rulemaking (FNPRM)* in this proceeding, which was previously published in the **Federal Register**.

DATES: Submit reply comments on or before August 15, 2014.

ADDRESSES: You may submit comments, identified by GN Docket No. 12–354 or FCC 14–49, by any of the following methods:

- *Federal Communications Commission's Web site:* <http://fjallfoss.fcc.gov/ecfs2/>. Follow the instructions for submitting comments.
- *Mail:* All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW., Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of before entering the building. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW., Washington, DC 20554.

- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: FCC504@fcc.gov or phone: 202–418–0530 or TTY: 202–418–0432.

FOR FURTHER INFORMATION CONTACT: Paul Powell, Attorney Advisor, Wireless

Bureau's Mobility Division, at (202) 418-1613 or email at Paul.Powell@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Wireless Telecommunications Bureau's document in GN Docket No. 12-354, DA 14-1071, adopted and released July 28, 2014, which extends the reply comment filing deadline established in the *FNPRM* published under FCC No. 14-49 at 79 FR 31247, June 2, 2014. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center, 445 12th Street SW., Washington, DC 20554. The complete text may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room CY-B402, Washington, DC 20554, (202) 488-5300, facsimile (202) 488-5563, or via email at fcc@bcpweb.com. The full text may also be downloaded at: www.fcc.gov. Alternative formats are available to persons with disabilities by sending an email to fcc504@fcc.gov or by calling the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

Summary

We extend the deadline for filing reply comments in response to the *Further Notice of Proposed Rulemaking (FNPRM)* to allow parties to more thoroughly address the complex technical, legal, and policy issues raised in the *FNPRM* and in the record. Interested parties will now have until August 15, 2014 to file reply comments.

On July 23, 2014, the Satellite Industry Association (SIA) filed a motion to extend the reply comment deadline for the *FNPRM* from August 1 until August 15, 2014. SIA asserts that additional time is needed to respond to significant technical issues raised in the extensive record. In addition, SIA notes that, during the scheduled reply comment period, many of the technical personnel responsible for analyzing issues raised in the *FNPRM* on behalf of SIA member companies will be unavailable. These personnel will be attending meetings of the ITU Joint Task Working Groups preparing for WRC-15.

On July 24, 2014, the Public Interest Spectrum Coalition, Utilities Telecom Council, and Wireless Internet Service Providers Association (Petitioners) filed a joint request (Joint Extension Request) to extend the reply comment deadline until August 15, 2014. Petitioners assert that extenuating circumstances warrant an extension and that the requested extension would be consistent with the public interest. Specifically, the Joint Extension Request asserts that additional time is needed to accurately assess and prepare responses to the relatively large volume of comments filed in response to the *FNPRM*, many of which addressed complicated technical issues. The Petitioners also note that the Commission's Electronic Comment Filing System was largely inaccessible during the two days following the July 14, 2014 comment deadline and that the **Federal Register** publication date of the *FNPRM* removed an additional two days from the contemplated reply comment window. In addition, the Petitioners note that many of the parties that have filed

comments in this proceeding have also been participating in the Open Internet proceeding and other Commission rulemakings with overlapping deadlines. The Petitioners contend that the requested extension would not prejudice other parties or delay consideration of the record and that the Commission's work would be assisted by more robust participation in the reply comment phase.

It is the general policy of the Commission that extensions of time shall not be routinely granted. *See* 47 CFR 1.46(a). However, under these circumstances, we agree that an extension of time to file reply comments is warranted to ensure that the Commission obtains a complete and thorough record in response to the *FNPRM*. The *FNPRM* sought comment on a wide variety of novel technical, policy and legal issues related to the establishment of the proposed Citizens Broadband Radio Service. We conclude that a short extension of time is warranted to enable interested parties sufficient opportunity to review and respond to the complex issues raised by the *FNPRM*. Accordingly, pursuant to section 4(i) of the Communications Act of 1934, 47 U.S.C. 154(i), as amended, and section 1.46 of the Commission's rules, 47 CFR 1.46, we extend the deadline for filing reply comments until August 15, 2014.

Federal Communications Commission.

John Leibovitz,

Deputy Chief, Wireless Telecommunications Bureau.

[FR Doc. 2014-18612 Filed 8-5-14; 8:45 am]

BILLING CODE 6712-01-P

Notices

Federal Register

Vol. 79, No. 151

Wednesday, August 6, 2014

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

July 31, 2014.

The Department of Agriculture will submit the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, Washington, DC; New Executive Office Building, 725–17th Street NW., Washington, DC, 20503. Commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@omb.eop.gov or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602.

Comments regarding these information collections are best assured of having their full effect if received by September 5, 2014. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Agricultural Marketing Service

Title: 7 CFR Part 54—Meats, Prepared Meats, and Meat Products (Grading, Certification, and Standards) and 7 CFR Part 62 Quality Systems Verification Programs (QSVP).

OMB Control Number: 0581–0124.

Summary of Collection: The Agricultural Marketing Act of 1946, as amended, authorizes the Secretary of Agriculture to provide consumers with voluntary Federal meat grading and certification services that facilitate the marketing of meat and meat products. This is accomplished by providing meat and meat products that are uniform in quality. The Meat Grading and Certification (MGC) Branch provides these services under the authority of 7 CFR Part 54—Meats, Prepared Meats, and Meat Products (Grading, Certification, and Standards). The Agricultural Marketing Service (AMS) will collect information using forms LS–313 and LS–315.

The Quality Systems Verification Programs are a collection of voluntary, audit-based, user-fee programs that allow applicants to have program documentation and program processes assessed by AMS auditors and other USDA officials. The QSVP are user-fees based on the approved hourly rate established under 7 CFR, Part 62.

Need and Use of the Information: The information AMS collects on LS–313, “Application for Service,” and LS–315, “Application for Commitment Grading or Certification Service” will enable the Agency to identify the responsible authorities in establishments requesting services and to initiate billing and collection accounts. A signed LS–313 or LS–315 form serves as a legal agreement between USDA users of the services, assures payment for services provided, and constitutes authorization for any employee of AMS to enter the establishment for the purpose of performing official functions under the regulations. Without a properly signed

and approved form, AMS officials would not have the authority to enter the premises to provide grading and/or certification services.

Description of Respondents: Business or other for-profit; Farms.

Number of Respondents: 83.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 1,330.

Agricultural Marketing Service

Title: Child Nutrition Labeling Program.

OMB Control Number: 0581–0261.

Summary of Collection: The Child Nutrition Labeling Program is a voluntary technical assistance program administered by the Agricultural Marketing Service (AMS). The program is designed to aid schools and institutions participating in the National School Lunch Program, the School Breakfast Program, the Child and Adult Care Food Program, and the Summer Food Service Program by, determining the contribution a commercial product makes towards the meal pattern requirements. Legislative authority for the programs is covered under The National School Lunch Act (NSLA); Public Law 90–302 enacted in 1968 amended the NSLA establishing the Special Food Service Program for Children. In 1975 Congress separated the Child Care Food Program and Summer Food Service components of the SFAPFC and provided each with legislative authorization.

The Child Nutrition Labeling Program is implemented in conjunction with existing label approval programs administered by the Food Safety and Inspection Service (FSIS), and the U.S. Department of Commerce (DoC). To participate in the CN Labeling Program, industry submits labels to AMS of products that are in conformance with the FSIS label approval program (for meat and poultry), and the DoC label approval program (for seafood products).

Need and Use of the Information: AMS uses the information collected to aid school food authorities and other institutions participating in child nutrition programs in determining the contribution a commercial product makes towards the established meal pattern requirements. AMS uses all of the collected information to give the submitted label an approval status that indicates if the label can be used as part

of the CN Labeling Program. Without the information CN Labeling Program would have no basis on which to determine how or if a product meets the meal pattern requirements.

Description of Respondents: Business or other for-profit.

Number of Respondents: 202.

Frequency of Responses: Reporting: Other (as needed).

Total Burden Hours: 758.

Agricultural Marketing Service

Title: Local Food Promotion Program.

OMB Control Number: 0581–0287.

Summary of Collection: The Agriculture Act of 2014 (Pub. L. 113–79) (2014 Farm Bill) amended the Farmer-to-Consumer Direct Marketing Act of 1976 (7 U.S.C. 3005) by expanding and renaming the Farmers' Market Promotion Program (FMPP) to Farmers' Market and Local Food Promotion Program (FMLFPP). The amended program will now include funding opportunities for projects that develop, improve, and expand local and regional food business enterprises that process, distribute, aggregate or store locally or regionally produced food products. A burden is being imposed on eligible entities that apply to and are awarded under the Local Food component of the FMLFPP. Approximately \$15 million will be made available for local and regional food business enterprise projects under the Local Food Promotion Program (LFPP).

Need and Use of the Information:

Two types of applications will be accepted under LFPP. The first type of application will be for planning grants and the second type will be for implementation grants. All forms must be submitted electronically via the Grants.gov Web site. Eligible entities for grants under LFPP include: Agricultural cooperatives, producer networks, producer associations, community supported agriculture networks, community supported agriculture associations, and other agricultural business entities (for profit groups); non-profit corporations; public benefit corporations; economic development corporations; regional farmers' market authorities; and local and Tribal governments. Without the required information, Agricultural Marketing Service will not be able to review, award, reimburse, or monitor grants to eligible applicants.

Description of Respondents: Business or other for-profit; Not-for-profit and State, Local and Tribal Government.

Number of Respondents: 1,500.

Frequency of Responses: Annually.

Total Burden Hours: 34,988.

Agricultural Marketing Service

Title: National Organic Program; Organic Certification Cost-Share Programs.

OMB Control Number: 0581–0288.

Summary of Collection: The National Organic Certification Cost Share Program (NOCCSP) is authorized under section 10606(d)(1) of the Farm Security and Rural Investment Act of 2002 (7 U.S.C. 7901 note), as amended by section 10004(c) of the Agriculture Act of 2014 (2014 Farm Bill: Pub. L. 113–79). Under this authority, USDA is authorized to provide organic certification cost-share assistance through 50 States, the District of Columbia, and five U.S. Territories. Collection requirements are applied only to those State Departments of Agriculture and organic producers and handlers who voluntarily participate in one of two organic certification cost-share programs: The NOCCSP or the Agricultural Management Assistance (AMA) Organic Certification Cost-Share Program. To prevent duplicate assistance payments, producers participating in the AMS program are not eligible to participate in the producer portion of the NOCCSP.

Need and Use of the Information: The information collection requirements in this request are applied only to those state agencies and organic producers and handlers who voluntarily participate in one of these programs for Fiscal Years 2014 to 2018. Each program provides cost-share assistance, through participating state agencies, to organic producers and, in the case of NOCCSP, to organic handlers. Recipients must receive initial certification or continuation of certification to the USDA organic regulations (7 CFR part 205) from a USDA-accredited certifying agent. The information collected from respondents is needed to ensure that program recipients are eligible for funding and comply with applicable program regulations.

Description of Respondents: State, Local and Tribal Government; Business or other for-profit; Not-for-profit.

Number of Respondents: 12,056.

Frequency of Responses:

Total Burden Hours: 16,592.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2014–18603 Filed 8–5–14; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2014–0010]

National Advisory Committee on Meat and Poultry Inspection; Committee Renewal

AGENCY: Food Safety and Inspection Service.

ACTION: Notice of the Reestablishment of the U.S. Department of Agriculture National Advisory Committee on Meat and Poultry Inspection.

SUMMARY: The U.S. Department of Agriculture intends to renew the National Advisory Committee on Meat and Poultry Inspection (NACMPI). The purpose of the Committee is to provide advice to the Secretary of Agriculture concerning State and Federal programs with respect to meat and poultry inspection, food safety, and other matters that fall within the scope of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA).

FOR FURTHER INFORMATION CONTACT: Ms. Natasha Williams, Management Analyst, Office of Outreach, Employee Education and Training, Food Safety and Inspection Service (FSIS), telephone (202) 690–6531; Fax (202) 690–6519; email Natasha.williams@fsis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

In accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App.), notice is hereby given that the Secretary of Agriculture intends to renew the National Advisory Committee on Meat and Poultry Inspection for two years. The Committee provides advice and recommendations to the Secretary on meat and poultry inspection programs, pursuant to sections 7(c), 24, 301(a)(3), and 301(c) of the Federal Meat Inspection Act, 21 U.S.C. 607(c), 624, 645, 661(a)(3), and 661(c), and to sections 5(a)(3), 5(c), 8(b), and 11(e) of the Poultry Products Inspection Act, 21 U.S.C. 454(a)(3), 454(c), 457(b), and 460(e).

A copy of the current charter and other information about the committee can be found at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/advisory-committees/nacmpi>

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at <http://www.fsis.usda.gov/wps/portal/fsis/home>

FSIS will also make copies of this **Federal Register** publication available

through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at <http://www.fsis.usda.gov/wps/portal/fsis/programs-and-services/email-subscription-service>.

Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Nondiscrimination Statement

USDA prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, or audiotape) should contact USDA's Target Center at 202-720-2600 (voice and TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250-9410 or call 202-720-5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Done at Washington, DC, July 31, 2014.

Alfred V. Almanza,
Administrator.

[FR Doc. 2014-18523 Filed 8-5-14; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Forest Service

Request for Applications: The Community Forest and Open Space Conservation Program

AGENCY: Forest Service.

ACTION: Request for applications.

SUMMARY: The U.S. Department of Agriculture, Forest Service, State and Private Forestry, Cooperative Forestry staff, requests applications for the Community Forest and Open Space Conservation Program (Community Forest Program or CFP). This is a competitive grant program whereby local governments, qualified nonprofit organizations, and Indian tribes are eligible to apply for grants to establish community forests through fee simple acquisition of private forest land from a willing seller. The purpose of the program is to establish community forests by protecting forest land from conversion to non-forest uses and provide community benefits. Some of these benefits include sustainable forest management; clean air, water, wildlife habitat, and other environmental benefits; forest-based educational programs; service as models of effective forest stewardship; and recreational benefits secured with public access.

Private forest land that is at least five acres in size, suitable to sustain natural vegetation, and at least 75 percent forested is considered eligible lands for grants funded under this program. The lands must also be threatened by conversion to non-forest use, must not be held in trust by the United States on behalf of any Indian tribe, must not be tribal allotment lands, must be offered for sale by a willing seller, and if acquired by an eligible entity, must provide defined community benefits under CFP and allow public access.

DATES: Interested local government and nonprofit applicants must submit applications to the State Forester. Tribal applicants must submit applications to the appropriate Tribal government officials. All applications, either hardcopy or electronic, must be received by State Foresters or Tribal governments by January 16, 2015. State Foresters or Tribal government officials must forward applications to the Forest Service Region, Northeastern Area, or International Institute of Tropical Forestry by February 17, 2015.

ADDRESSES: All local government and qualified nonprofit organization applications must be submitted to the State Forester of the State where the property is located. All Tribal applications must be submitted to the equivalent Tribal government official. Applicants are encouraged to contact and work with the Forest Service Region, Northeastern Area, or International Institute of Tropical Forestry, and State Forester or equivalent Tribal government official in developing their proposal. The State

Forester's contact information may be found at <http://www.fs.fed.us/spf/coop/programs/loa/cfp.shtml>. All applicants must also send an email to communityforest@fs.fed.us to confirm an application has been submitted for funding consideration.

State Foresters and Tribal government officials shall submit applications, either electronic or hardcopy, to the appropriate Forest Service Regional/Area/Institute contact noted below.

Northern and Intermountain Regions

Regions 1 and 4

(ID, MT, ND, NV, UT)

Janet Valle, U.S. Forest Service, 324 25th St., Ogden, UT 84401, 801-625-5258 (phone), 801-625-5716 (fax), jvalle@fs.fed.us.

Rocky Mountain Region

Region 2

(CO, KS, NE, SD, WY)

Claire Harper, U.S. Forest Service, 740 Simms Street, Golden, CO 80401, 303-275-5239 (phone), 303-275-5754 (fax), claireharper@fs.fed.us.

Southwestern Region

Region 3

(AZ, NM)

Margee Haines, U.S. Forest Service, 333 Broadway SE., Albuquerque, NM 87102, 505-842-3881 (phone), 505-842-3165 (fax), mhaines@fs.fed.us.

Pacific Southwest Region

Region 5

(CA, HI, Guam, American Samoa, Federated States of Micronesia and other Pacific Islands)

Dan McKeague, U.S. Forest Service, 1323 Club Drive, Vallejo, CA 94592, 707-562-8875 (phone), 707-562-9054 (fax), dmckeague@fs.fed.us.

Pacific Northwest, and Alaska Regions

Regions 6 and 10

(AK, OR, WA)

Brad Siemens, U.S. Forest Service, 120 Southwest 3rd Ave., Portland, OR 97204 or P.O. Box 3623, Portland, OR 97208-3623, 503-808-2353 (phone), 503-808-2469 (fax), btsiemens@fs.fed.us.

Southern Region

Region 8

(AL, AR, FL, GA, KY, LA, MS, NC, OK, SC, TN, TX, VA)

Mike Murphy, U.S. Forest Service, 1720 Peachtree Rd. NW., Suite 700B 850S North, Atlanta, GA 30309, 404-347-

5214 (phone), 404-347-2776 (fax),
mwmurphy@fs.fed.us.

International Institute of Tropical Forestry

(PR, VI)

Connie Carpenter, U.S. Forest Service,
Jardin Botanico Sur, 1201 Calle Ceiba,
San Juan, PR 00926-1119, 787-766-
5335 x 222 (phone), 787-766-6263
(fax), conniecarpenter@fs.fed.us.

Northeastern Area

(CT, DC, DE, IA, IL, IN, MA, MD, ME,
MI, MN, MO, NH, NJ, NY, OH, PA, RI,
VT, WI, WV)

Neal Bungard, U.S. Forest Service, 271
Mast Road, Durham, NH 03824-4600,
603-868-7719 (phone), 603-868-
7604 (fax), nbungard@fs.fed.us.

FOR FURTHER INFORMATION CONTACT: For
questions regarding the grant
application or administrative
regulations, contact Maya Solomon,
Program Coordinator, 202-205-1376,
mayasolomon@fs.fed.us.

Individuals who use
telecommunication devices for the deaf
(TDD) may call the Federal Relay
Service (FRS) at 1-800-877-8339
twenty-four hours a day, every day of
the year, including holidays.

SUPPLEMENTARY INFORMATION: *Catalog of
Federal Domestic Assistance (CFDA)*
number 10.689: To address the goals of
Section 7A of the Cooperative Forestry
Assistance Act of 1978 (16 U.S.C.
2103d) as amended, the Forest Service
is requesting proposals for community
forest projects that protect forest land
that has been identified as a national,
regional, or local priority for protection
and to assist communities in acquiring
forest land that will provide public
recreation, environmental and economic
benefits, and forest-based educational
programs.

Detailed information regarding what
to include in the application, definitions
of terms, eligibility, and necessary
prerequisites for consideration can be
found in the final program rule,
published October 20, 2011 (76 FR
65121-65133), which is available at
[www.fs.fed.us/spf/coop/programs/loa/
cfp.shtml](http://www.fs.fed.us/spf/coop/programs/loa/cfp.shtml) and at www.grants.gov
(Opportunity number CFP-FS-
1002015).

Grant Application Requirements

1. Eligibility Information

a. *Eligible Applicants.* A local
governmental entity, Indian Tribe
(including Alaska Native Corporations),
or a qualified nonprofit organization
that is qualified to acquire and manage
land (see 36 CFR 230.2). Individuals are

not eligible to receive funds through this
program.

b. *Cost Sharing (Matching
Requirement).* All applicants must
demonstrate a 50 percent match of the
total project cost. The match can
include cash, in-kind services, or
donations, which shall be from a non-
Federal source. For additional
information, please see 36 CFR 230.6, or
the final rule at [www.fs.fed.us/spf/coop/
programs/loa/cfp.shtml](http://www.fs.fed.us/spf/coop/programs/loa/cfp.shtml).

c. *DUNS Number.* All applicants shall
include a Data Universal Numbering
System (DUNS) number in their
application. For this requirement, the
applicant is the entity that meets the
eligibility criteria and has the legal
authority to apply for and receive the
grant. For assistance in obtaining a
DUNS number at no cost, call the DUNS
number request line 1-866-705-5711 or
register on-line at [http://fedgov.dnb.
com/webform](http://fedgov.dnb.com/webform).

d. *System for Award Management.* All
prospective awardees shall be registered
in the System for Award Management
prior to award, during performance, and
through final payment of any grant
resulting from this solicitation. Further
information can be found at
www.sam.gov. For assistance, contact
Federal Service Desk 1-866-606-8220.

2. Award Information

The Administration proposed to fund
the CFP at \$1.683 million for fiscal year
2015. Individual grant applications may
not exceed \$400,000, which does not
include technical assistance requests.
The Federal Government's obligation
under this program is contingent upon
the availability of appropriated funds.

No legal liability on the part of the
Government shall be incurred until
funds are committed by the Grant
Officer for this program to the applicant
in writing. The initial grant period shall
be for 2 years, and acquisition of lands
should occur within that timeframe.
Lands acquired prior to the grant award
are not eligible for CFP funding. The
grant may be reasonably extended by
the Forest Service when necessary to
accommodate unforeseen circumstances
in the land acquisition process. Written
annual financial performance reports
and semi-annual project performance
reports shall be required and submitted
to the appropriate Grant Officer.

Technical assistance funds, totaling
not more than 10 percent of all funds,
may be allocated to State Foresters and
equivalent officials of the Indian tribe.
Technical assistance, if provided, will
be awarded at the time of the grant.
Applicants shall work with the State
Foresters and equivalent officials of the
Indian tribe to determine technical

assistance needs and include the
technical assistance request in the
project budget.

As funding allows, applications
submitted through this request may be
funded in future years, subject to the
availability of funds and the continued
feasibility and viability of the project.

3. Application Information

Application submission. All local
governments and qualified nonprofit
organizations' applications must be
submitted to the State Forester where
the property is located by January 16,
2015. All Tribal applications must be
submitted to the equivalent Tribal
officials by January 16, 2015.
Applications may be submitted either
electronic or hardcopy to the
appropriate official. The State Forester's
contact information may be found at
[http://www.fs.fed.us/spf/coop/
programs/loa/cfp.shtml](http://www.fs.fed.us/spf/coop/programs/loa/cfp.shtml).

All applicants must also send an
email to communityforest@fs.fed.us to
confirm an application has been
submitted for funding consideration.

All State Foresters and Tribal
government officials must forward
applications to the Forest Service by
February 17, 2015.

4. Application Requirements

The following section outlines grant
application requirements:

a. The application can be no more
than eight pages long, plus no more than
two maps (eight and half inches by
eleven inches in size), the grant forms
specified in (b), and the draft
Community Forest Plan specified in (d).

b. The following grant forms and
supporting materials must be included
in the application:

- (1) An Application for Federal
Assistance (Standard Form 424);
- (2) Budget information (Standard
Form SF 424c—Construction Programs);
and
- (3) Assurances of compliance with all
applicable Federal laws, regulations,
and policies (Standard Form 424d—
Construction Programs).

c. Documentation to verify the
applicant is an eligible entity and that
the land proposed for acquisition is
eligible (see 36 CFR 230.2).

d. Applications must include the
following, regarding the property
proposed for acquisition:

- (1) A description of the property,
including acreage and county location;
- (2) A description of current land uses,
including improvements;
- (3) A description of forest type and
vegetative cover;
- (4) A map of sufficient scale to show
the location of the property in relation

to roads and other improvements as well as parks, refuges, or other protected lands in the vicinity;

(5) A description of applicable zoning and other land use regulations affecting the property;

(6) A description of the type and extent of community benefits, including to underserved communities (see selection criteria);

(7) A description of relationship of the property within and its contributions to a landscape conservation initiative; and

(8) A description of any threats of conversion to non-forest uses, including any encumbrances on the property that prevent conversion to nonforest uses.

e. Information regarding the proposed establishment of a community forest, including:

(1) A description of the benefiting community, including demographics, and the associated benefits provided by the proposed land acquisition;

(2) A description of community involvement to-date in the planning of the community forest acquisition and of community involvement anticipated long-term management;

(3) An identification of persons and organizations that support the project and their specific role in establishing and managing the community forest; and

(4) A draft Community Forest Plan. The eligible entity is encouraged to work with the State Forester or equivalent Tribal government official for technical assistance when developing or updating the Community Forest Plan. In addition, the eligible entity is encouraged to work with technical specialists, such as professional foresters, recreation specialists, wildlife biologists, or outdoor education specialists, when developing the Community Forest Plan.

f. Information regarding the proposed land acquisition, including:

(1) A proposed project budget not exceeding \$400,000 and technical assistance needs as coordinated with the State Forester or equivalent Tribal government official. (36 CFR 230.6);

(2) The status of due diligence, including signed option or purchase and sale agreement, title search, minerals determination, and appraisal;

(3) Description and status of cost share (secure, pending, commitment letter, etc.) (36 CFR 230.6);

(4) The status of negotiations with participating landowner(s) including purchase options, contracts, and other terms and conditions of sale;

(5) The proposed timeline for completing the acquisition and establishing the community forest; and

(6) Long term management costs and funding source(s).

g. Applications must comply with the Uniform Federal Assistance Regulations (7 CFR part 3015).

h. Applications must also include the forms required to process a Federal grant. Section 230.7 references the grant forms that must be included in the application and the specific administrative requirements that apply to the type of Federal grant used for this program.

A sample grant application sample outline and scoring guidance can be found on the CFP Web site at: <http://www.fs.fed.us/spf/coop/programs/loa/cfp.shtml>.

5. Forest Service's Project Selection Criteria

a. Using the criteria described below, to the extent practicable, the Forest Service will give priority to applications that maximize the delivery of community benefits, as defined in 36 CFR 230.2; and

b. The Forest Service will evaluate all applications received by the State Foresters or equivalent Tribal government officials and award grants based on the following criteria:

(1) Type and extent of community benefits provided, including to underserved communities. Community benefits are defined in the final program rule as:

(i) Economic benefits such as timber and non-timber products;

(ii) Environmental benefits, including clean air and water, storm water management, and wildlife habitat;

(iii) Benefits from forest-based experiential learning, including K-12 conservation education programs; vocational education programs in disciplines such as forestry and environmental biology; and environmental education through individual study or voluntary participation in programs offered by organizations such as 4-H, Boy or Girl Scouts, Master Gardeners, etc;

(iv) Benefits from serving as replicable models of effective forest stewardship for private landowners; and

(v) Recreational benefits such as hiking, hunting and fishing secured through public access.

(2) Extent and nature of community engagement in the establishment and long-term management of the community forest;

(3) Amount of cost share leveraged;

(4) Extent to which the community forest contributes to a landscape conservation initiative;

(5) Extent of due diligence completed on the project, including cost share committed and status of appraisal;

(6) Likelihood that, unprotected, the property would be converted to non-forest uses; and

(7) Costs to the Federal Government.

6. Grant Requirements

a. Once an application is selected, funding will be obligated to the grant recipient through a grant.

b. Local and Indian tribal governments should refer to 2 CFR part 225, Cost Principles for State, Local, and Indian Tribal Governments (OMB Circular A-87) and 7 CFR part 3016, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments for directions.

c. Non-profit organizations should refer to 2 CFR part 215, Uniform Administrative Requirements for Grants and Other Agreements with Institutions of Higher Education, Hospitals and Other Nonprofit Organizations (OMB Circular A-110) and 7 CFR part 3019 Uniform Administrative Requirements for Grants and Cooperative Agreements with Institutions of Higher Education, Hospitals, and other Non-profit Organizations for directions.

d. The Forest Service must approve any amendments to a proposal or request to reallocate funding within a grant proposal. If negotiations on a selected project fail, the applicant cannot substitute an alternative site.

e. The grant recipient must comply with the requirements in 36 CFR 230.8 before funds will be released.

f. After the project has closed, as a requirement of the grant, grant recipients will be required to provide the Forest Service with a Geographic Information System (GIS) shapefile: A digital, vector-based storage format for storing geometric location and associated attribute information of CFP project tracts and cost share tracts, if applicable.

g. Any funds not expended within the grant period must be de-obligated and revert to the Forest Service.

h. All media, press, signage, and other documents discussing the creation of the community forest must reference the partnership and financial assistance by the Forest Service through the CFP.

Additional information may be found in 36 CFR 230.9.

Dated: July 30, 2014.

Robert Bonnie,
Under Secretary, Natural Resources and Environment.

[FR Doc. 2014-18539 Filed 8-5-14; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE**Forest Service****Angeles National Forest; Los Angeles County, CA Williamson Rock/Pacific Crest National Scenic Trail (PCT) Project EIS****AGENCY:** Forest Service, USDA.**ACTION:** Notice of intent to prepare an Environmental Impact Statement.

SUMMARY: The Angeles National Forest proposes to provide limited, managed recreational activities in the vicinity of Williamson Rock. The proposed action would include allowing access to the Pacific Crest National Scenic Trail (PCT) and limited access to Williamson Rock for rock climbing, while protecting the federally listed mountain yellow-legged frog (MYLF) and other unique resources. The area has been closed to the public since 2006, either by Forest Order or court injunction, to protect the MYLF.

The project was originally proposed as an environmental assessment, and an opportunity for public scoping comments was provided from December 18, 2013 through January 24, 2014. Preliminary issues identified during scoping indicated that there may be significant effects resulting from the proposed action. Responsible official, Forest Supervisor Thomas A. Contreras, has decided to prepare an EIS instead of an EA for this project. The proposed action in the EA has been modified for the EIS.

DATES: Comments on the proposed action should be submitted within 30 days of the date of publication of this Notice of Intent in the **Federal Register**. The Draft Environmental Impact Statement (EIS) is expected to be available for public review in Spring 2015 and the Final EIS is expected in Fall 2015.

ADDRESSES: You may submit comments by one of the following methods:

- Mailed to the Angeles National Forest; Attn: Jose Henriquez, Williamson Rock/PCT ID Team; 701 N. Santa Anita Avenue, Arcadia, CA 91006;
- Delivered to the address shown above during business hours (M–F 8:00 a.m. to 4:30 p.m.);
- Submitted electronically, in common formats (.doc, .pdf, .rtf, .txt), to: comments-pacificsouthwest-angeles@fs.fed.us with Subject: Williamson Rock.

FOR FURTHER INFORMATION CONTACT: Jose Henriquez, 701 N. Santa Anita Avenue, Arcadia, CA 91006; (626) 574–5277. A scoping package, maps and other information are online at: http://www.fs.fed.us/nepa/nepa_project_exp.php?project=43405.

[fed.us/nepa/nepa_project_exp.php?project=43405](http://www.fs.fed.us/nepa/nepa_project_exp.php?project=43405).

SUPPLEMENTARY INFORMATION:

General Background: Williamson Rock is a well-known High Country recreation area used predominately for rock climbing, located within the Santa Clara-Mojave Rivers Ranger District, in upper Little Rock Canyon. It has been utilized by climbers since the 1960's and is regarded as one of the unique rock climbing resources in southern California, due to its mild summer temperatures and close proximity to urban centers. The Pacific Crest National Scenic Trail (PCT) traverses the project area, paralleling and periodically crossing Little Rock Creek and its tributaries for approximately 2 miles. The mountain yellow-legged frog (*Rana muscosa*—MYLF) occupies habitat in Little Rock Creek, within the Williamson Rock area. The area is also home to a nesting pair of peregrine falcons (*Falco peregrinus*), as well as a Forest Service Sensitive plant species, Johnston's buckwheat (*Eriogonum microthecum* var. *johnstonii*).

Purpose and Need for Action: The Forest Service continues to receive high demand for the resumption of recreation opportunities in the Williamson Rock area. Specifically, there is a need for the public use and enjoyment of the PCT where it passes through the project area, in accordance with the management objectives specified in the PCTA/Forest Service Memorandum of Understanding and PCT Comprehensive Management Plan. Consistent with the Angeles National Forest Land Management Plan recreation goals and objectives, there is also a need for a quality, sustainable rock climbing opportunity at Williamson Rock.

In achieving these needs, this proposal and any alternatives must achieve the following purposes:

- Provide protective measures for the federally listed MYLF, and the Primary Constituent Elements of the Designated Critical Habitat in the project area.
- Protect other listed or otherwise unique resources in the Williamson Rock area (specifically: Peregrine falcon, Johnston's buckwheat, and an eligible Wild and Scenic River).
- Monitor recreation activity to manage compliance of natural resource protective measures.

Proposed Action: In meeting the needs for action, the following measures are proposed:

1. **Implement long-term closure of Little Rock Creek corridor and adjacent areas.**
 - Implement a long-term closure of the stream corridor (10 meters beyond

high water mark) within MYLF Designated Critical Habitat (DCH) and adjacent areas between the stream corridor and CA–2 within Section 12, T. 3N, R. 10W and Section 7, T.3N, R. 11W as shown on maps #1 and #2 (see http://www.fs.fed.us/nepa/nepa_project_exp.php?project=43405). These are areas that have historically provided direct human access into the DCH, or contain climbing routes within the stream habitat. The closure would include all stream-based rock climbing routes (e.g. the “Stream Wall” and “London Wall”), as well as the area of “user-created” braided trails and paths along scree slopes between CA–2 and Williamson Rock. Exceptions to this closure are as follows:

- Exception: The Pacific Crest National Scenic Trail (PCT) is within the proposed closure area, and would remain open year around (see further discussion of the PCT below).
- Exception: The Long Trail, a new system trail which would access the Williamson Rock Visitor Use Permit Area, would be within the proposed closure boundaries, and would remain open from August 1 to November 15 to people having a valid Visitor Use Permit (see further discussion of the Long Trail below).

2. **Implement a visitor use permit system and seasonal closures for the Williamson Rock Visitor Use Permit Area.**

- Designate a day-use Visitor Use Permit Area that encompasses the Williamson Rock Trailhead and parking, the Long Trail, and the Williamson Rock climbing areas as shown on maps #1 and #2 (see http://www.fs.fed.us/nepa/nepa_project_exp.php?project=43405). Visitors to this area would be required to obtain a Visitor Use Permit through the National Recreation Reservation Service (NRRS).

- A seasonal closure of the Visitor Use Permit Area would be implemented from November 16 to July 31, to minimize impacts to MYLF and/or peregrine falcons.

- During the open season (August 1 to November 15), Visitor Use Permits would be reserved in advance through NRRS online or by calling the NRRS toll-free number. Permits would not be issued by local Forest Service offices.

- At least one Forest Service site manager with citation authorization would be onsite each day that the Visitor Use Permit Area is open. Funding for this site management would be provided by a combination of grants, partner contributions, user fees, and federal budget allocations.

- The Forest Service would use the NRRS system to provide permit users

with educational information about the area, including regulations, human waste disposal requirements, and resource protection concerns and requirements.

- A limited number of permits would be issued each day, based on site capacity (including parking capacity at the Kratka Ridge parking lot on CA-2). The permit system would be governed by an “either/or” quota mechanism that would initially issue permits each day for no more than 90 persons to access the rock and no more than 30 vehicles (based on available number of parking stalls) to park at the designated trail head.

- The number of visitor use permits issued would be adjusted up or down as determined by an adaptive management process that would consider the following three metrics/indicators:

- MYLF population reports
- Permit compliance
- Available funding for onsite Forest Service management

- Dogs and other domestic animals would be prohibited (PCT exempt), unless they are service animals covered under DOJ 28 CFR Part 35.136—also applies to federal agencies under Section 504.

3. Provide developed recreation facilities to access Williamson Rock.

- Establish a system trail (approximately 1.2 miles in length) to the east side of Williamson Rock from the Kratka Ridge parking lot, partially using abandoned logging road segments and the user-created trail alignment currently referred to as the Long Trail (see map #2 at http://www.fs.fed.us/nepa/nepa_project_exp.php?project=43405).

- The Long Trail would cross Little Rock Creek in two places (referred to in this analysis as the 1st and 2nd crossings). At the 2nd crossing, install a removable 3'–4' wide by approximately 14' long stream crossing platform. The platform would be built so that it could be easily removed and re-installed based on the seasonal closure periods. See sample images of platform crossings in the fact sheet posted at http://www.fs.fed.us/nepa/nepa_project_exp.php?project=43405.

- At the 1st stream crossing, materials deposited over several years create an artificial bridge that would continue to be used as a stream crossing. The material keeps people out of the stream, and it has also been determined that removing the material could create more resource damage than if left in place.

- Place interpretive signage and barriers to discourage entry into closure areas and encourage resource protection.

- At the terminus of the Long Trail at Williamson Rock, install an information kiosk displaying a map of the existing climbing routes available for use, site use etiquette and rules, and clearly identified closed areas.

4. Construct Pacific Crest National Scenic Trail bridge.

- Construct a bridge for PCT users at the point where the trail crosses Little Rock Creek within the closure area (SW $\frac{1}{4}$, Section 12, T. 3N, R. 10W). See map and image of proposed bridge location in the fact sheet posted at http://www.fs.fed.us/nepa/nepa_project_exp.php?project=43405.

5. Manage human waste.

- Removal of human waste would be required in the Williamson Rock Visitor Use Permit Area and along the Long Trail corridor. Permit holders must bag and remove all human waste (feces) and toilet paper, and deposit in a disposal container to be installed at the Kratka Ridge trailhead/parking area. The presence of human waste in these areas would be monitored to determine compliance.

- Install a vault toilet at the Kratka Ridge trailhead/parking area.

- Provide interpretive signing within the Visitor Use Permit Area, trailhead/parking area, and along the Long Trail regarding human waste disposal requirements.

- Hikers on the PCT would be required to deposit human body waste in cat-holes dug at least 100 feet from any surface freshwater source, and to remove toilet paper as trash.

6. Implement botanical resource requirements (Include in all action alternatives).

- Sensitive plant species found within the project area shall be flagged and avoided prior to, and during construction activities.

- (1) All heavy equipment and vegetation maintenance tools (e.g., chain saws, hand clippers, pruners) shall be cleaned prior to entering National Forest System lands. (2) Any transport vehicles that have operated in an off-road area since that vehicle's last washing shall be cleaned prior to entering National Forest System lands.

- Cutting or removal of trees shall be done by or under the direction of a silviculturist.

- Install and maintain appropriate weed free erosion/sediment control measures, as needed per the erosion control plan, throughout the duration of work activities. Wattles or hay bales shall be made of rice straw and netted in biodegradable material.

- If necessary, barriers will be installed or replaced to limit unauthorized off-highway vehicle

activity after trail construction activities.

- During the growing season following trail construction, a survey for weed species would be conducted along the trail and associated disturbance areas to ensure that new/expanding weed species are removed/controlled.

7. Prevent access to user-created trails.

- Install natural barriers at access points to user-created trails within the project area, to prevent use and encourage natural regeneration.

- Monitor trespass activity to determine if additional measures would be needed.

8. Develop a monitoring and adaptive management plan.

- A monitoring and adaptive management plan for the closure area and Williamson Rock Visitor User Permit Area would be developed and adopted as a part of implementation, to determine appropriate use levels and seasons over time.

Possible Alternatives: In addition to the proposed action, the EIS will evaluate the required No Action alternative and will likely consider other alternatives identified through the interdisciplinary process and public participation.

Responsible Official: Thomas A. Contreras, Forest Supervisor, Angeles National Forest, Supervisor's Office, 701 N. Santa Anita Avenue, Arcadia, CA 91006.

Nature of Decision to be Made: The responsible official will decide whether to adopt and implement the proposed action, or an alternative to the proposed action, or take no action with respect to the Williamson Rock/PCT project.

Scoping Process

This notice of intent initiates the scoping process, which guides the development of the environmental impact statement. The Forest Service is soliciting comments from federal, state and local agencies and other individuals or organizations that may be interested in or affected by implementation of the proposed project.

Public questions and comments regarding this proposal are an integral part of this environmental analysis process. Input provided by interested and/or affected individuals, organizations and governmental agencies will be used to identify resource issues that will be analyzed in the environmental impact statement. The Forest Service will identify significant issues raised during the scoping process, and use them to formulate alternatives, prescribe mitigation measures and project design

features, or analyze environmental effects.

We are particularly interested in hearing about any potential issues, which are defined as points of discussion, dispute, or debate about the effects of the proposed action. Your participation will help the interdisciplinary team develop effective, issue-driven alternatives and mitigations to the proposed action as needed. It is important that reviewers provide their comments at such times and in such a manner that they are useful to the agency's preparation of the environmental impact statement. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions.

The project was originally proposed as an environmental assessment, and an opportunity for public scoping comments was provided between December 18, 2013 and January 24, 2014. The proposed action in the EA has been modified for the EIS. If you previously commented on the project, your comments have been and will continue to be considered in the development of alternatives. In order to move forward with this project, we ask that you do not repeat your comments. Following alternative development, the Forest Service will be providing another opportunity to comment on the alternatives and analysis. If you have any new comments, we welcome those at this time.

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public project record for this proposed action. Comments submitted anonymously will be accepted and considered; however, anonymous comments will not provide the agency with the ability to provide the respondent with subsequent environmental documents.

Dated: July 29, 2014.

Thomas A. Contreras,
Forest Supervisor.

[FR Doc. 2014-18553 Filed 8-5-14; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE

Forest Service

Wallowa-Whitman National Forest; Oregon; Notice of Intent To Prepare a Supplement to the 2012 Final Environmental Impact Statement for Snow Basin Vegetation Management Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare a supplemental environmental impact statement.

SUMMARY: The USDA Forest Service will prepare a Supplement to the Snow Basin Vegetation Management Project Final Environmental Impact Statement (EIS) to address the environmental impact of the project on elk and elk habitat, as directed by the United States Court of Appeals for the Ninth Circuit in *League of Wilderness Defenders/Blue Mountains Biodiversity Project v. Connaughton*, 752 F.3d 755, 767 (9th Cir. 2014). Specifically, the court held that 'plaintiffs are likely to prevail on their claim that a supplemental EIS must be completed to show the environmental impact of the Snow Basin project on elk and their habitat now that the [Travel Management Plan] has been withdrawn.' *Id.* at 761.

FOR FURTHER INFORMATION CONTACT: Dea Nelson, Environmental Coordinator, Wallowa-Whitman National Forest, PO Box 907, Baker City, OR 97814; or, 541-523-1216; or, dnelson09@fs.fed.us.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: In March 2012, the Final EIS for the Snow Basin Vegetation Management Project was completed. A Record of Decision was signed on March 19, 2012. These documents, which include descriptions of the purpose and need for the project and the proposed action, can be found at <http://www.fs.usda.gov/goto/SnowBasin>. The supplemental EIS will provide additional information to clarify the impacts on elk of the Snow Basin project without considering the travel management plan decision, which was withdrawn in April 2012. A draft supplemental EIS is estimated to be available in November 2014, and the final in February 2015.

Responsible Official

Wallowa-Whitman Forest Supervisor.

Nature of Decision To Be Made

The Responsible Official will decide whether or not to incorporate the supplemental information into the FEIS. The Responsible Official will also document the decision and reasons for the decision in a new record of decision consistent with the scope of the supplement. This decision will be subject to Forest Service predecisional objection procedures (36 CFR part 218, Subparts A and B).

Scoping Process

Scoping is not required for supplements to environmental impact statements (40 CFR 1502.9(c)(4)). Scoping was conducted for the original EIS. The supplement will be subject to notice and comment. A draft supplemental EIS will be published and made available for review and comment for 45 days, following direction at 36 CFR part 218 § 218.22 and § 218.24.

Dated: July 29, 2014.

John Laurence,
Forest Supervisor.

[FR Doc. 2014-18577 Filed 8-5-14; 8:45 am]

BILLING CODE 3410-11-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-570-938]

Citric Acid and Certain Citrate Salts From the People's Republic of China: Final Results of Expedited Sunset Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce ("the Department") finds that revocation of the countervailing duty order ("CVD") order on citric acid and certain citrate salts ("citric acid") from the People's Republic of China ("PRC") would be likely to lead to continuation or recurrence of a countervailable subsidy at the levels indicated in the "Final Results of Review" section of this notice.

Effective Date: August 6, 2014.

FOR FURTHER INFORMATION CONTACT: Patricia Tran, Office III, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482-1503.

SUPPLEMENTARY INFORMATION:

Background

On April 1, 2014, the Department initiated a sunset review of the CVD order on citric acid from the PRC pursuant to section 751(c) of the Tariff Act of 1930, as amended (“the Act”).¹ The Department received a notice of intent to participate in the review on behalf of Archer Daniels Midland Company, Cargill, Incorporated, and Tate & Lyle Ingredients Americas LLC, (collectively, “the domestic industry”) within the deadline specified in 19 CFR 351.218(d)(1)(i). Each of these companies claimed interested party status under section 771(9)(C) of the Act, as a domestic producer of the domestic like product.

The Department received adequate substantive responses collectively from the domestic industry within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i). The Department did not receive a substantive response from any government or respondent interested party to the proceeding. Because the Department received no response from the respondent interested parties, the Department conducted an expedited review of this CVD order, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2).

Scope of the Order

The merchandise subject to the order is citric acid and certain citrate salts. The product is currently classified under the Harmonized Tariff Schedule of the United States (“HTSUS”) item numbers 2918.14.0000, 2918.15.1000, 2918.15.5000, 3824.90.9290, and 3824.90.9290. Although the HTSUS numbers are provided for convenience and customs purposes, the written product description remains dispositive.

For a full description of the scope, see “Issues and Decision Memorandum for the Final Results of Expedited Sunset Review of the Countervailing Duty Order on Citric Acid and Certain Citrate Salts from the People’s Republic of China” from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, dated concurrently with this final notice, and hereby adopted by this notice (“Issues and Decision Memorandum”).

Analysis of Comments Received

All issues raised in this review are addressed in the Issues and Decision Memorandum. The issues discussed in the Issues and Decision Memorandum include the likelihood of continuation

or recurrence of a countervailable subsidy and the net countervailable subsidy likely to prevail if the order were revoked. Parties can find a complete discussion of all issues raised in this expedited sunset review and the corresponding recommendations in this public memorandum which is on file electronically via the Enforcement and Compliance Antidumping and Countervailing Duty Centralized Electronic Service System (IA ACCESS). IA ACCESS is available to registered users at <http://iaaccess.trade.gov> and in the Central Records Unit, Room 7046 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at <http://enforcement.trade.gov/frn/index.html>. The signed Issues and Decision Memorandum and the electronic versions of the Issues and Decision Memorandum are identical in content.

Final Results of Review

We determine that revocation of the CVD order on citric acid from the PRC would be likely to lead to continuation or recurrence of a countervailable subsidy at the rates listed below:

Exporter/manufacturer	Net subsidy rate
TTCA Co., Ltd. (a.k.a. Shandong TTCA Biochemistry Co., Ltd.)	44.31 percent <i>ad valorem</i> .
Yixing Union Biochemical Co., Ltd.; and Yixing Union Cogeneration Co., Ltd	36.46 percent <i>ad valorem</i> .
Anhui BBKA Biochemical Co., Ltd	150.58 percent <i>ad valorem</i> .
All Others	39.77 percent <i>ad valorem</i> .

Notification Regarding Administrative Protective Order

This notice 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 return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing the results and notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act.

Dated: July 30, 2014.

Paul Piquado,

Assistant Secretary, for Enforcement and Compliance.

[FR Doc. 2014–18594 Filed 8–5–14; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–824, A–583–837, C–533–825]

Polyethylene Terephthalate Film, Sheet and Strip From India and Taiwan: Continuation of Antidumping and Countervailing Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* August 6, 2014.

SUMMARY: As a result of the determinations by the Department of

Commerce (the Department) and the International Trade Commission (ITC) that revocation of the antidumping duty and countervailing duty orders on Polyethylene Terephthalate Film, Sheet and Strip (PET Film) from India and the antidumping duty order on PET Film from Taiwan, would likely lead to a continuation or recurrence of dumping and material injury to an industry in the United States, the Department is publishing a notice of continuation for these antidumping and countervailing duty orders.

Contact Information: Jacqueline Arrowsmith, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC 20230; telephone (202) 482–5255.

SUPPLEMENTARY INFORMATION:

¹ See *Initiation of Five-Year (“Sunset”) Review*, 79 FR 18279 (April 1, 2014).

Background

The Department initiated and the ITC instituted sunset reviews of the antidumping duty orders on PET Film from India and Taiwan and the countervailing duty order on PET Film from India, pursuant to section 751(c) and 752 of the Tariff Act of 1930, as amended (the Act).¹

As a result of its review, the Department found that revocation of the countervailing duty order would likely lead to a continuation or recurrence of net countervailable subsidies, and therefore, notified the ITC of the subsidy rate were the order to be revoked.² As a result of its review, the Department found that revocation of the antidumping duty orders on PET Film from India and Taiwan would likely lead to a continuation or recurrence of dumping and, therefore, notified the ITC of the magnitude of the margins likely to prevail were the orders to be revoked.³

On July 22, 2014, the ITC published its determination pursuant to sections 751(c) and 752 of the Act, that revocation of the antidumping duty order on PET Film from India and Taiwan would likely lead to a continuation or recurrence of dumping and the countervailing duty order on PET Film from India would likely lead to a continuation or recurrence of net countervailable subsidies.⁴

Scope of the Orders

The products covered by the antidumping duty and countervailing duty orders are all gauges of raw, pretreated, or primed PET Film, whether extruded or coextruded. Excluded are metallized films and other finished films that have had at least one of their surfaces modified by the application of a performance-enhancing resinous or inorganic layer of more than 0.00001 inches thick. Imports of PET Film are currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under item number 3920.62.00.90. HTSUS subheadings are provided for convenience and customs purposes. The

written description of the scope of the antidumping duty order is dispositive.

Scope Determinations

Since these orders were published, there was one scope determination for PET film from India, dated August 25, 2003. In this determination, requested by International Packaging Films Inc., the Department determined that tracing and drafting film is outside of the scope of the order on PET Film from India.⁵

Continuation of the Orders

As a result of the determinations by the Department and the ITC that revocation of the antidumping duty orders and the countervailing duty order would likely lead to a continuation or recurrence of dumping and net countervailable subsidies and material injury to an industry in the United States, pursuant to sections 751(c) and 751(d)(2) of the Act, the Department hereby orders the continuation of these antidumping duty orders on PET film from India and Taiwan and the countervailing duty order on PET Film from India. U.S. Customs and Border Protection will continue to collect antidumping duty and countervailing duty cash deposits at the rates in effect at the time of entry for all imports of subject merchandise.

The effective date of the continuation of this order will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act, the Department intends to initiate the next five-year review of this order not later than 30 days prior to the fifth anniversary of the effective date of continuation.

This five-year (sunset) review and this notice are in accordance with section 751(c) of the Act and published pursuant to section 777(i)(1) of the Act and 19 CFR 351.218(f)(4).

Dated: July 29, 2014.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2014–18599 Filed 8–5–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–853; A–570–937]

Citric Acid and Certain Citrate Salts From Canada and the People's Republic of China: Final Results of Expedited First Sunset Reviews of the Antidumping Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of these sunset reviews, the Department of Commerce (the Department) finds that revocation of the antidumping duty orders on citric acid and certain citrate salts (citric acid) from Canada and the People's Republic of China (PRC) would be likely to lead to continuation or recurrence of dumping. The magnitude of the dumping margins likely to prevail is indicated in the "Final Results of Sunset Reviews" section of this notice.

DATES: *Effective Date:* August 6, 2014.

FOR FURTHER INFORMATION CONTACT: Terre Keaton Stefanova or Katherine Johnson, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1280 or (202) 482–4929, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 29, 2009, the Department published in the **Federal Register** the antidumping duty orders on citric acid from Canada and the PRC.¹ On April 1, 2014, the Department published the notice of initiation of the first sunset reviews of the antidumping duty orders on citric acid from Canada and the PRC pursuant to section 751(c) of the Tariff Act of 1930, as amended ("the Act").² On April 14, 2014, the Department received Notices of Intent to Participate in these reviews from the following domestic producers of citric acid: Archer Daniels Midland Company, Cargill, Incorporated, and Tate & Lyle Ingredients Americas LLC. (collectively, "the petitioners"), within the deadline specified in 19 CFR 351.218(d)(1)(i). The petitioners claimed interested party status under section 771(9)(C) of the Act, as manufacturers of a domestic like

¹ See *Initiation of Five Year ("Sunset") Review*, 78 FR 19647 (April 2, 2013).

² See *Polyethylene Terephthalate (PET) Film, Sheet and Strip From India: Final Results of the Expedited Second Sunset Review of the Countervailing Duty Order*, 78 FR 47276 (August 5, 2013).

³ See *Polyethylene Terephthalate Film, Sheet and Strip From India and Taiwan: Final Results of the Second Sunset Review of the Antidumping Duty Orders and Correction to the Preliminary Results*, 79 FR 12153 (March 4, 2014).

⁴ See *Polyethylene Terephthalate Film, Sheet and Strip From India and Taiwan*, 79 FR 42534 (July 22, 2014).

⁵ See *Notice of Scope Rulings*, 70 FR 24533 (May 10, 2005).

¹ See *Citric Acid and Certain Citrate Salts from Canada and the People's Republic of China: Antidumping Duty Orders*, 74 FR 25703 (May 29, 2009).

² See *Initiation of Five-Year ("Sunset") Review*, 79 FR 18279 (April 1, 2014).

product in the United States. On May 1, 2014, we received a complete substantive response for each review from the petitioners within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).³ We received no substantive responses from any respondent interested parties. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), the Department conducted expedited (120-day) sunset reviews of these orders.

Scope of the Orders

The merchandise covered by these orders is citric acid and certain citrate salts. The product is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) at item numbers 2918.14.0000 and 2918.15.1000, 2918.15.5000 and

3824.90.9290. Although the HTSUS numbers are provided for convenience and for customs purposes, the written description of the merchandise is dispositive. A complete description of the scope of these Orders is contained in the Decision Memo.⁴

Analysis of Comments Received

A complete discussion of all issues raised in these reviews is provided in the accompanying Decision Memo. The issues discussed in the Decision Memo include the likelihood of continuation or recurrence of dumping and the magnitude of the margins likely to prevail if these orders were to be revoked. The Decision Memo is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System

(IA ACCESS). IA ACCESS is available to registered users at <http://iaaccess.trade.gov>, and it is available to all parties in the Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a complete version of the Decision Memo can be accessed directly at <http://enforcement.trade.gov/frn/index.html>. The signed and electronic versions of the Decision Memo are identical in content.

Final Results of Sunset Reviews

We determine that revocation of the antidumping duty orders on citric acid from Canada and the PRC would be likely to lead to continuation or recurrence of dumping at the following weighted-average percentage margins:

Exporter/producer	Percent margin
Canada:	
Jungbunzlauer Canada Inc	23.21
All Others	23.21
PRC: ⁵	
TTCA Co., Ltd. (a.k.a. Shandong TTCA Biochemistry Co., Ltd.)/TTCA Co., Ltd. (a.k.a. Shandong TTCA Biochemistry Co., Ltd.)	129.08
Yixing Union Biochemical Co., Ltd./Yixing Union Biochemical Co., Ltd	94.61
Anhui BBBCA Biochemical Co., Ltd./Anhui BBBCA Biochemical Co., Ltd	111.85
Anhui BBBCA Biochemical Co., Ltd./China BBBCA Maanshan Biochemical Corp	111.85
A.H.A. International Co., Ltd./Yixing Union Biochemical Co., Ltd	111.85
A.H.A. International Co., Ltd./Nantong Feiyu Fine Chemical Co., Ltd	111.85
High Hope International Group Jiangsu Native Produce IMP & EXP Co., Ltd./Yixing Union Biochemical Co., Ltd	111.85
Huangshi Xinghua Biochemical Co., Ltd./Huangshi Xinghua Biochemical Co., Ltd	111.85
Lianyungang JF International Trade Co., Ltd./TTCA Co., Ltd. (a.k.a Shandong TTCA Biochemistry Co., Ltd.)	111.85
Laiwu Taihe Biochemistry Co., Ltd./Laiwu Taihe Biochemistry Co., Ltd	111.85
Lianyungang Shuren Scientific Creation Import & Export Co., Ltd./Lianyungang Great Chemical Industry Co., Ltd	111.85
Penglai Marine Bio-Tech Co. Ltd./Penglai Marine Bio-Tech Co. Ltd	111.85
RZBC Imp & Exp. Co., Ltd./RZBC Co., Ltd./RZBC (Juxian) Co., Ltd./RZBC Co., Ltd	111.85
RZBC Imp & Exp. Co., Ltd./RZBC Co., Ltd./RZBC (Juxian) Co., Ltd./RZBC (Juxian) Co., Ltd	111.85
RZBC Imp & Exp. Co., Ltd./RZBC Co., Ltd./RZBC (Juxian) Co., Ltd./Lianyungang Great Chemical Industry Co., Ltd	111.85
Shihezi City Changyun Biochemical Co., Ltd./Shihezi City Changyun Biochemical Co., Ltd	111.85
Weifang Ensign Industry Co., Ltd./Weifang Ensign Industry Co., Ltd	111.85
PRC-Wide Entity	156.87

Administrative Protective Order

This notice also serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective orders is hereby requested. Failure to comply

with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing these results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act.

Dated: July 30, 2014.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2014-18588 Filed 8-5-14; 8:45 am]

BILLING CODE 3510-DS-P

³ See the May 1, 2014, responses from the petitioners regarding the Five-Year ("Sunset") Review of Antidumping Duty Order on Citric Acid and Certain Citrate Salts from Canada: Domestic Industry's Substantive Response and the Five-Year ("Sunset") Review of Antidumping Duty Order on Citric Acid and Certain Citrate Salts from the

People's Republic of China: Domestic Industry's Substantive Response.

⁴ Memorandum to Paul Piquado, Assistant Secretary for Enforcement and Compliance, from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, titled "Issues and Decision Memorandum for the Final Results of the Expedited First Sunset Reviews

of the Antidumping Duty Orders on Citric Acid and Certain Citrate Salts from Canada and the People's Republic of China," dated concurrently with and adopted by this notice (Decision Memo).

⁵ The cash deposit rate for all PRC companies named below, except for Yixing Union Biochemical Co., Ltd./Yixing Union Biochemical Co., Ltd., were adjusted to account for export subsidies.

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

RIN 0648–XD393

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to a Pier Maintenance Project

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 a request from the U.S. Navy (Navy) for authorization to take marine mammals incidental to construction activities as part of a pier maintenance project. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to the Navy to incidentally take marine mammals, by Level B Harassment only, during the specified activity.

DATES: Comments and information must be received no later than September 5, 2014.

ADDRESSES: Comments on the application should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Physical comments should be sent to 1315 East-West Highway, Silver Spring, MD 20910 and electronic comments should be sent to ITP.Laws@noaa.gov.

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments received electronically, including all attachments, must not exceed a 25-megabyte file size. Attachments to electronic comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. All comments received are a part of the public record and will generally be posted to the Internet at www.nmfs.noaa.gov/pr/permits/incidental.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.

FOR FURTHER INFORMATION CONTACT: Ben Laws, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:**Availability**

An electronic copy of the Navy's application and supporting documents, as well as a list of the references cited in this document, may be obtained by visiting the Internet at: www.nmfs.noaa.gov/pr/permits/incidental.htm. In case of problems accessing these documents, please call the contact listed above.

National Environmental Policy Act (NEPA)

The Navy prepared an Environmental Assessment (EA; 2013) for this project. We subsequently adopted the EA and signed our own Finding of No Significant Impact (FONSI) prior to issuing the first IHA for this project, in accordance with NEPA and the regulations published by the Council on Environmental Quality. Information in the Navy's application, the Navy's EA, and this notice collectively provide the environmental information related to proposed issuance of this IHA for public review and comment. All documents are available at the aforementioned Web site. We will review all comments submitted in response to this notice as we complete the NEPA process, including a decision of whether to reaffirm the existing FONSI, prior to a final decision on the incidental take authorization request.

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 by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified area, the incidental, but not intentional, taking of small numbers of marine mammals, providing that certain findings are made and the necessary prescriptions are established.

The incidental taking of small numbers of marine mammals may be allowed only if NMFS (through authority delegated by the Secretary) finds that the total taking by the specified activity during the specified time period will (i) have a negligible impact on the species or stock(s) and (ii) not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant). Further, the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such taking must be set

forth, either in specific regulations or in an authorization.

The allowance of such incidental taking under section 101(a)(5)(A), by harassment, serious injury, death, or a combination thereof, requires that regulations be established. Subsequently, a Letter of Authorization may be issued pursuant to the prescriptions established in such regulations, providing that the level of taking will be consistent with the findings made for the total taking allowable under the specific regulations. Under section 101(a)(5)(D), NMFS may authorize such incidental taking by harassment only, for periods of not more than one year, pursuant to requirements and conditions contained within an IHA. The establishment of prescriptions through either specific regulations or an authorization requires notice and opportunity for public comment.

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, section 3(18) of the MMPA defines “harassment” as: “. . . any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [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 June 16, 2014, we received a request from the Navy for authorization to take marine mammals incidental to pile driving and removal associated with the Pier 6 pile replacement project at Naval Base Kitsap Bremerton, WA (NBKB). Hereafter, it may be assumed that use of the generic term “pile driving” refers to both pile driving and removal unless referring specifically to pile installation. The Navy submitted a revised version of the request on July 29, 2014, which we deemed adequate and complete. In-water work associated with the project would be conducted over three years and would occur only during the approved in-water work window from June 15 to March 1 of any year. This proposed IHA covers only the second year (in-water work window) of the project, and would be valid from October 1, 2014, through March 1, 2015.

The use of both vibratory and impact pile driving is expected to produce underwater sound at levels that have the potential to result in behavioral harassment of marine mammals. Species with the expected potential to be present during all or a portion of the in-water work window include the Steller sea lion (*Eumetopias jubatus monteriensis*), California sea lion (*Zalophus californianus*), and harbor seal (*Phoca vitulina richardii*). All of these species may be present throughout the proposed period of validity for this IHA.

This would be the second such IHA, if issued, following the IHA issued effective from December 1, 2013, through March 1, 2014 (78 FR 69825). A monitoring report, provided as Appendix D of the Navy's application, is available on the Internet at www.nmfs.noaa.gov/pr/permits/incidental.htm and provides environmental information related to proposed issuance of this IHA for public review and comment.

Description of the Specified Activity

Overview

NBKB serves as the homeport for a nuclear aircraft carrier and other Navy vessels and as a shipyard capable of overhauling and repairing all types and sizes of ships. Other significant capabilities include alteration, construction, deactivation, and dry-docking of naval vessels. Pier 6 was completed in 1926 and requires substantial maintenance to maintain readiness. Over the length of the entire project, the Navy proposes to remove up to 400 deteriorating fender piles and to replace them with up to 330 new prestressed concrete fender piles.

Dates and Duration

The allowable season for in-water work, including pile driving, at NBKB is June 15 through March 1, a window established by the Washington Department of Fish and Wildlife in coordination with NMFS and the U.S. Fish and Wildlife Service (USFWS) to protect fish. The total three-year project is expected to require 25 days of vibratory pile removal and 77 days of impact pile driving. Under the proposed action—which includes only the portion of the project that would be completed under this proposed IHA—a maximum of sixty pile driving days would occur. The Navy proposes to conduct 15 days of vibratory pile removal and 45 days of pile installation with an impact hammer. Either type of pile driving may occur on any day during the proposed period of validity, including concurrent

pile removal and installation. Pile driving would occur only during daylight hours.

Specific Geographic Region

NBKB is located on the north side of Sinclair Inlet in Puget Sound (see Figures 1–1 and 2–1 of the Navy's application). Sinclair Inlet, an estuary of Puget Sound extending 3.5 miles southwesterly from its connection with the Port Washington Narrows, connects to the main basin of Puget Sound through Port Washington Narrows and then Agate Pass to the north or Rich Passage to the east. Sinclair Inlet has been significantly modified by development activities. Fill associated with transportation, commercial, and residential development of NBKB, the City of Bremerton, and the local ports of Bremerton and Port Orchard has resulted in significant changes to the shoreline. The area surrounding Pier 6 is industrialized, armored and adjacent to railroads and highways. Sinclair Inlet is also the receiving body for a wastewater treatment plant located just west of NBKB. Sinclair Inlet is relatively shallow and does not flush fully despite freshwater stream inputs.

Detailed Description of Activities

The Navy plans to remove deteriorated fender piles at Pier 6 and replace them with prestressed concrete piles. The entire project calls for the removal of 380 12-in diameter creosoted timber piles and twenty 12-in steel pipe piles. These would be replaced with 240 18-in square concrete piles and ninety 24-in square concrete piles. It is not possible to specify accurately the number of piles that might be installed or removed in any given work window, due to various delays that may be expected during construction work and uncertainty inherent to estimating production rates. The Navy assumes a notional production rate of sixteen piles per day (removal) and four piles per day (installation) in determining the number of days of pile driving expected, and scheduling—as well as exposure analyses—is based on this assumption.

All piles are planned for removal via vibratory driver. The driver is suspended from a barge-mounted crane and positioned on top of a pile. Vibration from the activated driver loosens the pile from the substrate. Once the pile is released, the crane raises the driver and pulls the pile from the sediment. Vibratory extraction is expected to take approximately 5–30 minutes per pile. If piles break during removal, the remaining portion may be removed via direct pull or with a clamshell bucket. Replacement piles

would be installed via impact driver and would require approximately 15–60 minutes of driving time per pile, depending on subsurface conditions. Impact driving and/or vibratory removal could occur on any work day during the period of the proposed IHA. Only one pile driving rig is planned for operation at any given time.

Description of Work Accomplished—During the first in-water work season, the contractor completed installation of two concrete piles, on two separate days. Please see the Navy's report in Appendix D of their application. The Navy initially estimated that 200 work days would be required to complete the project, but has revised that estimate downwards to 102 total days. Therefore, if the Navy completes sixty days of in-water work during year two of the project, we would anticipate that the project would be completed in a third year, with forty additional work days.

Description of Marine Mammals in the Area of the Specified Activity

There are five marine mammal species with records of occurrence in waters of Sinclair Inlet in the action area. These are the California sea lion, harbor seal, Steller sea lion, gray whale (*Eschrichtius robustus*), and killer whale (*Orcinus orca*). The harbor seal is a year-round resident of Washington inland waters, including Puget Sound, while the sea lions are absent for portions of the summer. For the killer whale, both transient (west coast stock) and resident (southern stock) animals have occurred in the area. However, southern resident animals are known to have occurred only once, with the last confirmed sighting from 1997 in Dyes Inlet. A group of 19 whales from the L–25 subpod entered and stayed in Dyes Inlet, which connects to Sinclair Inlet northeast of NBKB, for 30 days. Dyes Inlet may be reached only by traversing from Sinclair Inlet through the Port Washington Narrows, a narrow connecting body that is crossed by two bridges, and it was speculated at the time that the whales' long stay was the result of a reluctance to traverse back through the Narrows and under the two bridges. There is one other unconfirmed report of a single southern resident animal occurring in the project area, in January 2009. Of these stocks, the southern resident killer whale is listed (as endangered) under the Endangered Species Act (ESA).

An additional seven species have confirmed occurrence in Puget Sound, but are considered rare to extralimital in Sinclair Inlet and the surrounding waters. These species—the humpback whale (*Megaptera novaeangliae*), minke

whale (*Balaenoptera acutorostrata scammoni*), Pacific white-sided dolphin (*Lagenorhynchus obliquidens*), harbor porpoise (*Phocoena phocoena vomerina*), Dall's porpoise (*Phocoenoides dalli dalli*), and northern elephant seal (*Mirounga angustirostris*)—along with the southern resident killer whale, are considered extremely unlikely to occur in the action area or to be affected by the specified activities, and are not considered further in this document. A review of sightings records available from the Orca Network (www.orcanetwork.org; accessed July 14, 2014) confirms that there are no recorded observations of these species in the action area (with the exception of the southern resident sightings described above).

We have reviewed the Navy's detailed species descriptions, including life

history information, for accuracy and completeness and refer the reader to Sections 3 and 4 of the Navy's application instead of reprinting the information here. Please also refer to NMFS' Web site (www.nmfs.noaa.gov/pr/species/mammals) for generalized species accounts and to the Navy's Marine Resource Assessment for the Pacific Northwest, which documents and describes the marine resources that occur in Navy operating areas of the Pacific Northwest, including Puget Sound (DoN, 2006). The document is publicly available at www.navfac.navy.mil/products_and_services/ev/products_and_services/marine_resources/marine_resource_assessments.html (accessed May 2, 2014).

Table 1 lists the marine mammal species with expected potential for

occurrence in the vicinity of NBKB during the project timeframe and summarizes key information regarding stock status and abundance. Taxonomically, we follow Committee on Taxonomy (2014). Please see NMFS' Stock Assessment Reports (SAR), available at www.nmfs.noaa.gov/pr/sars, for more detailed accounts of these stocks' status and abundance. The harbor seal, California sea lion, and gray whale are addressed in the Pacific SARs (e.g., Carretta *et al.*, 2013a), while the Steller sea lion and transient killer whale are treated in the Alaska SARs (e.g., Allen and Angliss, 2013a).

In the species accounts provided here, we offer a brief introduction to the species and relevant stock as well as available information regarding population trends and threats, and describe any information regarding local occurrence.

TABLE 1—MARINE MAMMALS POTENTIALLY PRESENT IN THE VICINITY OF NBKB

Species	Stock	ESA/ MMPA status; Strategic (Y/N) ¹	Stock abundance (CV, N _{min} , most recent abundance survey) ²	PBR ³	Annual M/SI ⁴	Relative occurrence in sinclair inlet; season of occurrence
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)						
Family Eschrichtiidae: Gray whale	Eastern North Pacific ...	—; N	19,126 (0.071; 18,017; 2007)	558	127 ¹¹	Rare; year-round
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae: Killer whale	West coast transient ^{5,6}	—; N	243 (n/a; 2006)	2.4	0	Rare; year-round
Order Carnivora—Super- family Pinnipedia: Family Otariidae (eared seals and sea lions): California sea lion ...	U.S.	—; N	296,750 (n/a; 153, 337; 2008)	9,200	≥431	Common; year-round (excluding July)
Steller sea lion	Eastern U.S. ⁵	—; N ⁸	63,160–78,198 (n/a; 57,966; 2008–11) ⁹	1,552 ¹⁰	65.1	Occasional/seasonal; Oct–May
Family Phocidae (ear- less seals): Harbor seal	Washington inland waters ⁷ .	—; N	14,612 (0.15; 12,844; 1999)	771	13.4	Common; year-round

¹ ESA status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (—) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR (see footnote 3) or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

² CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, CV is not applicable. For killer whales, the abundance values represent direct counts of individually identifiable animals; therefore there is only a single abundance estimate with no associated CV. For certain stocks of pinnipeds, abundance estimates are based upon observations of animals (often pups) ashore multiplied by some correction factor derived from knowledge of the species' (or similar species') life history to arrive at a best abundance estimate; therefore, there is no associated CV. In these cases, the minimum abundance may represent actual counts of all animals ashore.

³ Potential biological removal, defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population size (OSP).

⁴ These values, found in NMFS' SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (e.g., commercial fisheries, subsistence hunting, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value. All values presented here are from the draft 2013 SARs (www.nmfs.noaa.gov/pr/sars/draft.htm).

⁵ Abundance estimates (and resulting PBR values) for these stocks are new values presented in the draft 2013 SARs. This information was made available for public comment and is currently under review and therefore may be revised prior to finalizing the 2013 SARs. However, we consider this information to be the best available for use in this document.

⁶ The abundance estimate for this stock includes only animals from the "inner coast" population occurring in inside waters of southeastern Alaska, British Columbia, and Washington—excluding animals from the "outer coast" subpopulation, including animals from California—and therefore should be considered a minimum count. For comparison, the previous abundance estimate for this stock, including counts of animals from California that are now considered outdated, was 354.

⁷ Abundance estimates for these stocks are greater than eight years old and are therefore not considered current. PBR is considered undetermined for these stocks, as there is no current minimum abundance estimate for use in calculation. We nevertheless present the most recent abundance estimates and PBR values, as these represent the best available information for use in this document.

⁸ The eastern distinct population segment of the Steller sea lion, previously listed under the ESA as threatened, was delisted on December 4, 2013 (78 FR 66140; November 4, 2013). Because this stock is not below its OSP size and the level of direct human-caused mortality does not exceed PBR, this delisting action implies that the stock is no longer designated as depleted or as a strategic stock under the MMPA.

⁹ Best abundance is calculated as the product of pup counts and a factor based on the birth rate, sex and age structure, and growth rate of the population. A range is presented because the extrapolation factor varies depending on the vital rate parameter resulting in the growth rate (i.e., high fecundity or low juvenile mortality).

¹⁰ PBR is calculated for the U.S. portion of the stock only (excluding animals in British Columbia) and assumes that the stock is not within its OSP. If we assume that the stock is within its OSP, PBR for the U.S. portion increases to 2,069.

¹¹ Includes annual Russian harvest of 123 whales.

Steller Sea Lion

Steller sea lions are distributed mainly around the coasts to the outer continental shelf along the North Pacific rim from northern Hokkaido, Japan through the Kuril Islands and Okhotsk Sea, Aleutian Islands and central Bering Sea, southern coast of Alaska and south to California (Loughlin *et al.*, 1984). Based on distribution, population response, and phenotypic and genotypic data, two separate stocks of Steller sea lions are recognized within U.S. waters, with the population divided into western and eastern distinct population segments (DPS) at 144°W (Cape Suckling, Alaska) (Loughlin, 1997). The eastern DPS extends from California to Alaska, including the Gulf of Alaska, and is the only stock that may occur in the Hood Canal.

According to NMFS' recent status review (NMFS, 2013), the best available information indicates that the overall abundance of eastern DPS Steller sea lions has increased for a sustained period of at least three decades while pup production has also increased significantly, especially since the mid-1990s. Johnson and Gelatt (2012) provided an analysis of growth trends of the entire eastern DPS from 1979–2010, indicating that the stock increased during this period at an annual rate of 4.2 percent (90% CI 3.7–4.6). Most of the overall increase occurred in the northern portion of the range (southeast Alaska and British Columbia), but pup counts in Oregon and California also increased significantly (e.g., Merrick *et al.*, 1992; Sease *et al.*, 2001; Olesiuk and Trites, 2003; Fritz *et al.* 2008; Olesiuk, 2008; NMFS, 2008, 2013). In Washington, Pitcher *et al.* (2007) reported that Steller sea lions, presumably immature animals and non-breeding adults, regularly used four haul-outs, including two "major" haul-outs (>50 animals). The same study reported that the numbers of sea lions counted between 1989 and 2002 on Washington haul-outs increased significantly (average annual rate of 9.2 percent) (Pitcher *et al.*, 2007). Although the stock size has increased, its status relative to OSP size is unknown. However, the consistent long-term

estimated annual rate of increase may indicate that the stock is reaching OSP size (Allen and Angliss, 2013a).

Data from 2005–10 show a total mean annual mortality rate of 5.71 (CV = 0.23) sea lions per year from observed fisheries and 11.25 reported takes per year that could not be assigned to specific fisheries, for an approximate total from all fisheries of 17 eastern Steller sea lions (Allen and Angliss, 2013a). In addition, opportunistic observations and stranding data indicate that an additional 32 animals are killed or seriously injured each year through interaction with commercial and recreational troll fisheries and by entanglement (Allen and Angliss, 2013b). The annual average take for subsistence harvest in Alaska was 11.9 individuals in 2004–08 (Allen and Angliss, 2013a). Data on community subsistence harvests is no longer being collected, and this average is retained as an estimate for current and future subsistence harvest. Sea lion deaths are also known to occur because of illegal shooting, vessel strikes, or capture in research gear and other traps, totaling 4.2 animals per year from 2007–11 (Allen and Angliss, 2013b). The total annual human-caused mortality is a minimum estimate because takes via fisheries interactions and subsistence harvest in Canada are poorly known, although are believed to be small.

The eastern stock breeds in rookeries located in southeast Alaska, British Columbia, Oregon, and California. There are no known breeding rookeries in Washington (Allen and Angliss, 2013a) but eastern stock Steller sea lions are present year-round along the outer coast of Washington, including immature animals or non-breeding adults of both sexes. In 2011, the minimum count for Steller sea lions in Washington was 1,749 (Allen and Angliss, 2013b), up from 516 in 2001 (Pitcher *et al.*, 2007). In Washington, Steller sea lions primarily occur at haul-out sites along the outer coast from the Columbia River to Cape Flattery and in inland waters sites along the Vancouver Island coastline of the Strait of Juan de Fuca (Jeffries *et al.*, 2000; Olesiuk and Trites, 2003; Olesiuk, 2008). Numbers vary

seasonally in Washington waters with peak numbers present during the fall and winter months (Jeffries *et al.*, 2000). More recently, five winter haul-out sites used by adult and subadult Steller sea lions have been identified in Puget Sound (see Figure 4–2 of the Navy's application). Numbers of animals observed at all of these sites combined were less than 200 individuals. The closest haul-out, with approximately 30 to 50 individuals near the Navy's Manchester Fuel Depot, occurs approximately 6.5 mi from the project site but is physically separated by various land masses and waterways. However, one Steller sea lion was observed hauled out on the floating security barrier at NBKB in November 2012. No permanent haul-out has been identified in the project area and Steller sea lion presence is considered to be rare and seasonal.

Harbor Seal

Harbor seals inhabit coastal and estuarine waters and shoreline areas of the northern hemisphere from temperate to polar regions. The eastern North Pacific subspecies is found from Baja California north to the Aleutian Islands and into the Bering Sea. Multiple lines of evidence support the existence of geographic structure among harbor seal populations from California to Alaska (e.g., O'Corry-Crowe *et al.*, 2003; Temte, 1986; Calambokidis *et al.*, 1985; Kelly, 1981; Brown, 1988; Lamont, 1996; Burg, 1996). Harbor seals are generally non-migratory, and analysis of genetic information suggests that genetic differences increase with geographic distance (Westlake and O'Corry-Crowe, 2002). However, because stock boundaries are difficult to meaningfully draw from a biological perspective, three separate harbor seal stocks are recognized for management purposes along the west coast of the continental U.S.: (1) Inland waters of Washington (including Hood Canal, Puget Sound, and the Strait of Juan de Fuca out to Cape Flattery), (2) outer coast of Oregon and Washington, and (3) California (Carretta *et al.*, 2013a). Multiple stocks are recognized in Alaska. Samples from Washington, Oregon, and California

demonstrate a high level of genetic diversity and indicate that the harbor seals of Washington inland waters possess unique haplotypes not found in seals from the coasts of Washington, Oregon, and California (Lamont *et al.*, 1996). Only the Washington inland waters stock may be found in the project area.

Recent genetic evidence suggests that harbor seals of Washington inland waters may have sufficient population structure to warrant division into multiple distinct stocks (Huber *et al.*, 2010, 2012). Based on studies of pupping phenology, mitochondrial DNA, and microsatellite variation, Carretta *et al.* (2013b) suggest division of the Washington inland waters stock into three new populations, and present these as prospective stocks: (1) Southern Puget Sound (south of the Tacoma Narrows Bridge); (2) Washington northern inland waters (including Puget Sound north of the Tacoma Narrows Bridge, the San Juan Islands, and the Strait of Juan de Fuca); and (3) Hood Canal. Until this stock structure is accepted, we consider a single Washington inland waters stock.

The best available abundance estimate was derived from aerial surveys of harbor seals in Washington conducted during the pupping season in 1999, during which time the total numbers of hauled-out seals (including pups) were counted (Jeffries *et al.*, 2003). Radio-tagging studies conducted at six locations collected information on harbor seal haul-out patterns in 1991–92, resulting in a pooled correction factor (across three coastal and three inland sites) of 1.53 to account for animals in the water which are missed during the aerial surveys (Huber *et al.*, 2001), which, coupled with the aerial survey counts, provides the abundance estimate (see Table 2).

Harbor seal counts in Washington State increased at an annual rate of six percent from 1983–96, increasing to ten percent for the period 1991–96 (Jeffries *et al.*, 1997). The population is thought to be stable, and the Washington inland waters stock is considered to be within its OSP size (Jeffries *et al.*, 2003).

Data from 2007–11 indicate that a minimum of four harbor seals are killed annually in Washington inland waters commercial fisheries, while mean annual mortality for recreational fisheries is one seal (Carretta *et al.*, 2013b). Animals captured east of Cape Flattery are assumed to belong to this stock. The estimate is considered a minimum because there are likely additional animals killed in unobserved fisheries and because not all animals stranding as a result of fisheries

interactions are likely to be recorded. Another 8.4 harbor seals per year are estimated to be killed as a result of various non-fisheries human interactions (Carretta *et al.*, 2013b). Tribal subsistence takes of this stock may occur, but no data on recent takes are available.

Harbor seal numbers increase from January through April and then decrease from May through August as the harbor seals move to adjacent bays on the outer coast of Washington for the pupping season. From April through mid-July, female harbor seals haul out on the outer coast of Washington at pupping sites to give birth. Harbor seals are expected to occur in Sinclair Inlet and NBKB at all times of the year. No permanent haul-out has been identified at NBKB. The nearest known haul-outs are along the south side of Sinclair Inlet on log breakwaters at several marinas in Port Orchard, approximately one mile from Pier 6. An additional haul-out location in Dyes Inlet, approximately 8.5 km north and west (shoreline distance), was believed to support less than 100 seals (Jeffries *et al.*, 2000). Please see Figure 4–2 of the Navy's application.

California Sea Lion

California sea lions range from the Gulf of California north to the Gulf of Alaska, with breeding areas located in the Gulf of California, western Baja California, and southern California. Five genetically distinct geographic populations have been identified: (1) Pacific temperate, (2) Pacific subtropical, and (3–5) southern, central, and northern Gulf of California (Schramm *et al.*, 2009). Rookeries for the Pacific temperate population are found within U.S. waters and just south of the U.S.-Mexico border, and animals belonging to this population may be found from the Gulf of Alaska to Mexican waters off Baja California. For management purposes, a stock of California sea lions comprising those animals at rookeries within the U.S. is defined (i.e., the U.S. stock of California sea lions) (Carretta *et al.*, 2013a). Pup production at the Coronado Islands rookery in Mexican waters is considered an insignificant contribution to the overall size of the Pacific temperate population (Lowry and Maravilla-Chavez, 2005).

Trends in pup counts from 1975 through 2008 have been assessed for four rookeries in southern California and for haul-outs in central and northern California. During this time period counts of pups increased at an annual rate of 5.4 percent, excluding six El Niño years when pup production

declined dramatically before quickly rebounding (Carretta *et al.*, 2013a). The maximum population growth rate was 9.2 percent when pup counts from the El Niño years were removed. There are indications that the California sea lion may have reached or is approaching carrying capacity, although more data are needed to confirm that leveling in growth persists (Carretta *et al.*, 2013a).

Data from 2003–09 indicate that a minimum of 337 (CV = 0.56) California sea lions are killed annually in commercial fisheries. In addition, a summary of stranding database records for 2005–09 shows an annual average of 65 such events, which is likely a gross underestimate because most carcasses are not recovered. California sea lions may also be removed because of predation on endangered salmonids (seventeen per year, 2008–10) or incidentally captured during scientific research (three per year, 2005–09) (Carretta *et al.*, 2013a). Sea lion mortality has also been linked to the algal-produced neurotoxin domoic acid (Scholin *et al.*, 2000). Future mortality may be expected to occur, due to the sporadic occurrence of such harmful algal blooms. There is currently an Unusual Mortality Event (UME) declaration in effect for California sea lions. Beginning in January 2013, elevated strandings of California sea lion pups have been observed in southern California, with live sea lion strandings nearly three times higher than the historical average. Findings to date indicate that a likely contributor to the large number of stranded, malnourished pups was a change in the availability of sea lion prey for nursing mothers, especially sardines. The causes and mechanisms of this UME remain under investigation (www.nmfs.noaa.gov/pr/health/mmume/californiasealions2013.htm; accessed May 8, 2014).

An estimated 3,000 to 5,000 California sea lions migrate northward along the coast to central and northern California, Oregon, Washington, and Vancouver Island during the non-breeding season from September to May (Jeffries *et al.*, 2000) and return south the following spring (Mate, 1975; Bonnell *et al.*, 1983). Peak numbers of up to 1,000 California sea lions occur in Puget Sound (including Hood Canal) during this time period (Jeffries *et al.*, 2000).

California sea lions were not recorded in Puget Sound until approximately 1979 (Steiger and Calambokidis, 1986). Everitt *et al.* (1980) reported the initial occurrence of large numbers in northern Puget Sound in the spring of that year. Similar sightings and increases in numbers were documented throughout

the region after the initial sighting (Steiger and Calambokidis 1986), including urbanized areas such as Elliot Bay near Seattle and heavily used areas of central Puget Sound (Gearin *et al.*, 1986). California sea lions now use haul-out sites within all regions of Washington inland waters (Jeffries *et al.*, 2000). California sea lions migrate northward along the coast to central and northern California, Oregon, Washington, and Vancouver Island during the non-breeding season from September to May and return south the following spring (Mate, 1975; Bonnell *et al.*, 1983). Jeffries *et al.* (2000) estimated that 3,000 to 5,000 individuals make this trip, with peak numbers of up to 1,000 occurring in Puget Sound during this time period. The California sea lion population has grown substantially, and it is likely that the numbers migrating to Washington inland waters have increased as well.

Occurrence in Puget Sound is typically between September and June with peak abundance between September and May. During summer months (June through August) and associated breeding periods, California sea lions are largely returning to rookeries in California and are not present in large numbers in Washington inland waters. They are known to utilize a diversity of man-made structures for hauling out (Riedman, 1990) and, although there are no regular California sea lion haul-outs known within Sinclair Inlet (Jeffries *et al.*, 2000), they are frequently observed hauled out at several opportune areas at NBKB (e.g., floating security fence; see Figures 4–1 and 4–2 of the Navy's application). The next nearest recorded haul-outs are navigation buoys and net pens in Rich Passage, approximately 10 km east of NBKB (Jeffries *et al.*, 2000).

Killer Whale

Killer whales are one of the most cosmopolitan marine mammals, found in all oceans with no apparent restrictions on temperature or depth, although they do occur at higher densities in colder, more productive waters at high latitudes and are more common in nearshore waters (Leatherwood and Dahlheim, 1978; Forney and Wade, 2006). Killer whales are found throughout the North Pacific, including the entire Alaska coast, in British Columbia and Washington inland waterways, and along the outer coasts of Washington, Oregon, and California. On the basis of differences in morphology, ecology, genetics, and behavior, populations of killer whales have largely been classified as “resident”, “transient”, or “offshore”

(e.g., Dahlheim *et al.*, 2008). Several studies have also provided evidence that these ecotypes are genetically distinct, and that further genetic differentiation is present between subpopulations of the resident and transient ecotypes (e.g., Barrett-Lennard, 2000). The taxonomy of killer whales is unresolved, with expert opinion generally following one of two lines: Killer whales are either (1) a single highly variable species, with locally differentiated ecotypes representing recently evolved and relatively ephemeral forms not deserving species status, or (2) multiple species, supported by the congruence of several lines of evidence for the distinctness of sympatrically occurring forms (Krahn *et al.*, 2004). Resident and transient whales are currently considered to be unnamed subspecies (Committee on Taxonomy, 2014).

The resident and transient populations have been divided further into different subpopulations on the basis of genetic analyses, distribution, and other factors. Recognized stocks in the North Pacific include Alaska residents; northern residents; southern residents; Gulf of Alaska, Aleutian Islands, and Bering Sea transients; and west coast transients, along with a single offshore stock. See Allen and Angliss (2013a) for more detail about these stocks. West coast transient killer whales, which occur from California through southeastern Alaska, are the only type expected to potentially occur in the project area.

It is thought that the stock grew rapidly from the mid-1970s to mid-1990s as a result of a combination of high birth rate, survival, as well as greater immigration of animals into the nearshore study area (DFO, 2009). The rapid growth of the population during this period coincided with a dramatic increase in the abundance of the whales' primary prey, harbor seals, in nearshore waters. Population growth began slowing in the mid-1990s and has continued to slow in recent years (DFO, 2009). Population trends and status of this stock relative to its OSP level are currently unknown. Analyses in DFO (2009) estimated a rate of increase of about six percent per year from 1975 to 2006, but this included recruitment of non-calf whales into the population.

Although certain commercial fisheries are known to have potential for interaction with killer whales and other mortality, resulting from shooting, ship strike, or entanglement, has been of concern in the past, the estimated level of human caused mortality and serious injury is currently considered to be zero for this stock (Allen and Angliss,

2013a). However, this could represent an underestimate as regards total fisheries-related mortality due to a lack of data concerning marine mammal interactions in Canadian commercial fisheries known to have potential for interaction with killer whales. Any such interactions are thought to be few in number (Allen and Angliss, 2013a). No ship strikes have been reported for this stock, and shooting of transients is thought to be minimal because their diet is based on marine mammals rather than fish. There are no reports of a subsistence harvest of killer whales in Alaska or Canada.

Transient occurrence in inland waters appears to peak during August and September which is the peak time for harbor seal pupping, weaning, and post-weaning (Baird and Dill, 1995). The number of west coast transients in Washington inland waters at any one time was considered likely to be fewer than twenty individuals by Wiles (2004), although more recent information (2004–10) suggests that transient use of inland waters has increased, possibly due to increasing prey abundance (Houghton *et al.*, in prep.). However, Sinclair Inlet is a shallow bay located approximately eight miles through various waterways from the main open waters of Puget Sound, where killer whales occur more frequently, and killer whale occurrence in Sinclair Inlet is uncommon. From December 2002 to June 2014, there were two reports of transient killer whales transiting through the area around NBKB, with both reports occurring in May (a group of up to twelve in 2004 and a group of up to five in 2012; www.orcanetwork.org).

Gray Whale

Gray whales are found in shallow coastal waters, migrating between summer feeding areas in the north and winter breeding areas in the south. Gray whales were historically common throughout the northern hemisphere but are now found only in the Pacific, where two populations are recognized, Eastern and Western North Pacific (ENP and WNP). ENP whales breed and calve primarily in areas off Baja California and in the Gulf of California. From February to May, whales typically migrate northbound to summer/fall feeding areas in the Chukchi and northern Bering Seas, with the southbound return to calving areas typically occurring in November and December. WNP whales are known to feed in the Okhotsk Sea and off of Kamchatka before migrating south to poorly known wintering grounds, possibly in the South China Sea.

The two populations have historically been considered geographically isolated from each other; however, recent data from satellite-tracked whales indicates that there is some overlap between the stocks. Two WNP whales were tracked from Russian foraging areas along the Pacific rim to Baja California (Mate *et al.*, 2011), and, in one case where the satellite tag remained attached to the whale for a longer period, a WNP whale was tracked from Russia to Mexico and back again (IWC, 2012). Between 22–24 WNP whales are known to have occurred in the eastern Pacific through comparisons of ENP and WNP photo-identification catalogs (IWC, 2012; Weller *et al.*, 2011; Burdin *et al.*, 2011), and WNP animals comprised 8.1 percent of gray whales identified during a recent field season off of Vancouver Island (Weller *et al.*, 2012). In addition, two genetic matches of WNP whales have been recorded off of Santa Barbara, CA (Lang *et al.*, 2011a). Therefore, a portion of the WNP population is assumed to migrate, at least in some years, to the eastern Pacific during the winter breeding season. However, no WNP whales are known to have occurred in Washington inland waters. The likelihood of any gray whale being exposed to project sound to the degree considered in this document is already low, given the uncommon occurrence of gray whales in the project area. In the event that a gray whale did occur in the project area, it is extremely unlikely that it would be one of the approximately twenty WNP whales that have been documented in the eastern Pacific (less than one percent probability). The WNP population is listed as endangered under the ESA and depleted under the MMPA as a foreign stock; however, the likelihood that a WNP whale would be present in the action area is insignificant and discountable.

In addition, recent studies provide new information on gray whale stock structure within the ENP, with emphasis on whales that feed during summer off the Pacific coast between northern California and southeastern Alaska, occasionally as far north as Kodiak Island, Alaska (Gosho *et al.*, 2011). These whales, collectively known as the Pacific Coast Feeding Group (PCFG), are a trans-boundary population with the U.S. and Canada and are defined by the International Whaling Commission (IWC) as follows: Gray whales observed between June 1 to November 30 within the region between northern California and northern Vancouver Island (from 41° N to 52° N) and photo-identified within this area during two or more years (Carretta *et al.*,

2013). Photo-identification and satellite tagging studies provide data on abundance, population structure, and movements of PCFG whales (Calambokidis *et al.*, 2010; Mate *et al.*, 2010; Gosho *et al.*, 2011). These data in conjunction with genetic studies (e.g., Frasier *et al.*, 2011; Lang *et al.*, 2011b) indicate that the PCFG may be a demographically distinct feeding aggregation, and may warrant consideration as a distinct stock (Carretta *et al.*, 2013). It is unknown whether PCFG whales would be encountered in Washington inland waters. Here, we consider only a single stock of ENP whales.

The ENP population of gray whales, which is managed as a stock, was removed from ESA protection in 1994, is not currently protected under the ESA, and is not listed as depleted under the MMPA. Punt and Wade (2010) estimated the ENP population was at 91 percent of carrying capacity and at 129 percent of the maximum net productivity level and therefore within the range of its optimum sustainable population. The estimated annual rate of increase from 1967–88, based on a revised abundance time series from Laake *et al.* (2009), is 3.2 percent (Punt and Wade, 2010), and the population size of the ENP gray whale stock has been increasing over the past several decades despite a west coast UME from 1999–2001. It is likely that oceanographic factors limited food availability (LeBouef *et al.*, 2000; Moore *et al.*, 2001; Minobe, 2002; Gulland *et al.*, 2005), with resulting declines in survival rates of adults (Punt and Wade, 2012). The population has recovered to levels seen prior to the UME (Carretta *et al.*, 2013b).

As noted above, gray whale numbers were significantly reduced by whaling, becoming extirpated from the Atlantic by the early 1700s and listed as an endangered species in the Pacific. Gray whales remain subject to occasional fisheries-related mortality and death from ship strikes. Based on stranding network data for the period 2007–11, there are an average of 2.4 deaths per year from the former and 2.0 per year from the latter. In addition, subsistence hunting of gray whales by hunters in Russia and the U.S. is approved by the IWC, although none is currently authorized in the U.S. From 2007–11, the annual Russian subsistence harvest was 123 whales (Carretta *et al.*, 2013). Climate change is considered a significant habitat concern for gray whales, as prey composition and distribution is likely to be altered and human activity in the whales' summer

feeding grounds increases (Carretta *et al.*, 2013).

Gray whales generally migrate southbound past Washington in late December and January, and transit past Washington on the northbound return in March to May. Gray whales do not generally make use of Washington inland waters, but have been observed in certain portions of those waters in all months of the year, with most records occurring from March through June (Calambokidis *et al.*, 2010; www.orcanetwork.org) and associated with regular feeding areas. Usually fewer than twenty gray whales visit the inner marine waters of Washington and British Columbia beginning in about January, with some staying until summer. Six to ten of these are PCFG whales that return most years to feeding sites near Whidbey and Camano Islands in northern Puget Sound. The remaining individuals occurring in any given year generally appear unfamiliar with feeding areas, often arrive emaciated, and commonly die of starvation (WDFW, 2012). From December 2002 to June 2014, the Orca Network sightings database reports four occurrences of gray whales in the project area during the in-water work window (www.orcanetwork.org). Three sightings occurred during the winter of 2008–09, and one stranding was reported in January 2013. The necropsy of the whale indicated that it was a juvenile male in poor nutritional health. Two other strandings have been recorded in the project area, in May 2005 and July 2011.

Potential Effects of the Specified Activity on Marine Mammals

This section includes a summary and discussion of the ways that components of the specified activity may impact marine mammals. This discussion also includes 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 “Estimated Take by Incidental Harassment” section later in this document will include a quantitative analysis of the number of individuals that are expected to be taken by this activity. The “Negligible Impact

Analysis" section will include the analysis of how this specific activity will impact marine mammals and will consider the content of this section, the "Estimated Take by Incidental Harassment" section, the "Proposed Mitigation" section, and the "Anticipated Effects on Marine Mammal Habitat" section to draw conclusions regarding the likely impacts of this activity on the reproductive success or survivorship of individuals and from that on the affected marine mammal populations or stocks. In the following discussion, we provide general background information on sound and marine mammal hearing before considering potential effects to marine mammals from sound produced by vibratory and impact pile driving.

Description of Sound Sources

Sound travels in waves, the basic components of which are frequency, wavelength, velocity, and amplitude. Frequency is the number of pressure waves that pass by a reference point per unit of time and is measured in hertz (Hz) or cycles per second. Wavelength is the distance between two peaks of a sound wave; lower frequency sounds have longer wavelengths than higher frequency sounds and attenuate (decrease) more rapidly in shallower water. Amplitude is the height of the sound pressure wave or the 'loudness' of a sound and is typically measured using the decibel (dB) scale. A dB is the ratio between a measured pressure (with sound) and a reference pressure (sound at a constant pressure, established by scientific standards). It is a logarithmic unit that accounts for large variations in amplitude; therefore, relatively small changes in dB ratings correspond to large changes in sound pressure. When referring to sound pressure levels (SPLs; the sound force per unit area), sound is referenced in the context of underwater sound pressure to 1 microPascal (μPa). One pascal is the pressure resulting from a force of one newton exerted over an area of one square meter. The source level (SL) represents the sound level at a distance of 1 m from the source (referenced to 1 μPa). The received level is the sound level at the listener's position. Note that all underwater sound levels in this document are referenced to a pressure of 1 μPa and all airborne sound levels in this document are referenced to a pressure of 20 μPa .

Root mean square (rms) is the quadratic mean sound pressure over the duration of an impulse. Rms is calculated by squaring all of the sound amplitudes, averaging the squares, and then taking the square root of the average (Urick, 1983). Rms accounts for

both positive and negative values; squaring the pressures makes all values positive so that they may be accounted for in the summation of pressure levels (Hastings and Popper, 2005). This measurement is often used in the context of discussing behavioral effects, in part because behavioral effects, which often result from auditory cues, may be better expressed through averaged units than by peak pressures.

When underwater objects vibrate or activity occurs, sound-pressure waves are created. These waves alternately compress and decompress the water as the sound wave travels. Underwater sound waves radiate in all directions away from the source (similar to ripples on the surface of a pond), except in cases where the source is directional. The compressions and decompressions associated with sound waves are detected as changes in pressure by aquatic life and man-made sound receptors such as hydrophones.

Even in the absence of sound from the specified activity, the underwater environment is typically loud due to ambient sound. Ambient sound is defined as environmental background sound levels lacking a single source or point (Richardson *et al.*, 1995), and the sound level of a region is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (e.g., waves, earthquakes, ice, atmospheric sound), biological (e.g., sounds produced by marine mammals, fish, and invertebrates), and anthropogenic sound (e.g., vessels, dredging, aircraft, construction). A number of sources contribute to ambient sound, including the following (Richardson *et al.*, 1995):

- Wind and waves: The complex interactions between wind and water surface, including processes such as breaking waves and wave-induced bubble oscillations and cavitation, are a main source of naturally occurring ambient noise for frequencies between 200 Hz and 50 kHz (Mitson, 1995). In general, ambient sound levels tend to increase with increasing wind speed and wave height. Surf noise becomes important near shore, with measurements collected at a distance of 8.5 km from shore showing an increase of 10 dB in the 100 to 700 Hz band during heavy surf conditions.

- Precipitation: Sound from rain and hail impacting the water surface can become an important component of total noise at frequencies above 500 Hz, and possibly down to 100 Hz during quiet times.

- Biological: Marine mammals can contribute significantly to ambient noise levels, as can some fish and shrimp. The

frequency band for biological contributions is from approximately 12 Hz to over 100 kHz.

- Anthropogenic: Sources of ambient noise related to human activity include transportation (surface vessels and aircraft), dredging and construction, oil and gas drilling and production, seismic surveys, sonar, explosions, and ocean acoustic studies. Shipping noise typically dominates the total ambient noise for frequencies between 20 and 300 Hz. In general, the frequencies of anthropogenic sounds are below 1 kHz and, if higher frequency sound levels are created, they attenuate rapidly (Richardson *et al.*, 1995). Sound from identifiable anthropogenic sources other than the activity of interest (e.g., a passing vessel) is sometimes termed background sound, as opposed to ambient sound.

The sum of the various natural and anthropogenic sound sources at any given location and time—which comprise "ambient" or "background" sound—depends not only on the source levels (as determined by current weather conditions and levels of biological and shipping activity) but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. As a result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10–20 dB from day to day (Richardson *et al.*, 1995). The result is that, depending on the source type and its intensity, sound from the specified activity may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals.

The underwater acoustic environment in Sinclair Inlet is likely to be dominated by noise from day-to-day port and vessel activities. Normal port activities include vessel traffic from large ships, submarines, support vessels, and security boats, and loading and maintenance operations. Other sources of human-generated underwater sound in the area are recreational vessels, industrial ship noise, and ferry traffic at the adjacent Washington State Ferry Terminal. In 2009, the average broadband (100 Hz–20 kHz) underwater noise level at NBK Bangor in the Hood Canal was measured at 114 dB (Slater, 2009), which is within the range of levels reported for a number of sites within the greater Puget Sound region

(95–135 dB; e.g., Carlson *et al.*, 2005; Veirs and Veirs, 2006). Measurements near ferry terminals in Puget Sound, such as the Bremerton terminal adjacent to NBKB, resulted in median noise levels (50% cumulative distribution function) between 106 and 133 dB (Laughlin, 2012). Although no specific measurements have been made at

NBKB, it is reasonable to believe that levels may generally be higher than at NBK Bangor as there is a greater degree of activity, that levels periodically exceed the 120-dB threshold and, therefore, that the high levels of anthropogenic activity in the area create an environment far different from quieter habitats where behavioral

reactions to sounds around the 120-dB threshold have been observed (e.g., Malme *et al.*, 1984, 1988).

Known sound levels and frequency ranges associated with anthropogenic sources similar to those that would be used for this project are summarized in Table 2. Details of the source types are described in the following text.

TABLE 2—REPRESENTATIVE SOUND LEVELS OF ANTHROPOGENIC SOURCES

Sound source	Frequency range (Hz)	Underwater sound level	Reference
Small vessels	250–1,000	151 dB rms at 1 m	Richardson <i>et al.</i> , 1995.
Tug docking gravel barge	200–1,000	149 dB rms at 100 m.	Blackwell and Greene, 2002.
Vibratory driving of 72-in steel pipe pile	10–1,500	180 dB rms at 10 m.	Reyff, 2007.
Impact driving of 36-in steel pipe pile	10–1,500	195 dB rms at 10 m.	Laughlin, 2007.
Impact driving of 66-in cast-in-steel-shell (CISS) pile	10–1,500	195 dB rms at 10 m.	Reviewed in Hastings and Popper, 2005.

In-water construction activities associated with the project would include impact pile driving and vibratory pile driving (removal only). The sounds produced by these activities fall into one of two general sound types: Pulsed and non-pulsed (defined in the following). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (e.g., Ward, 1997 in Southall *et al.*, 2007). Please see Southall *et al.*, (2007) for an in-depth discussion of these concepts.

Pulsed sound sources (e.g., explosions, gunshots, sonic booms, impact pile driving) produce signals that are brief (typically considered to be less than one second), broadband, atonal transients (ANSI, 1986; Harris, 1998; NIOSH, 1998; ISO, 2003; ANSI, 2005) and occur either as isolated events or repeated in some succession. Pulsed sounds are all characterized by a relatively rapid rise from ambient pressure to a maximal pressure value followed by a rapid decay period that may include a period of diminishing, oscillating maximal and minimal pressures, and generally have an increased capacity to induce physical injury as compared with sounds that lack these features.

Non-pulsed sounds can be tonal, narrowband, or broadband, brief or prolonged, and may be either continuous or non-continuous (ANSI, 1995; NIOSH, 1998). Some of these non-pulsed sounds can be transient signals of short duration but without the essential properties of pulses (e.g., rapid rise time). Examples of non-pulsed sounds include those produced by

vessels, aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar systems (such as those used by the U.S. Navy). The duration of such sounds, as received at a distance, can be greatly extended in a highly reverberant environment.

Impact hammers operate by repeatedly dropping a heavy piston onto a pile to drive the pile into the substrate. Sound generated by impact hammers is characterized by rapid rise times and high peak levels, a potentially injurious combination (Hastings and Popper, 2005). Vibratory hammers install piles by vibrating them and allowing the weight of the hammer to push them into the sediment. Vibratory hammers produce significantly less sound than impact hammers. Peak SPLs may be 180 dB or greater, but are generally 10 to 20 dB lower than SPLs generated during impact pile driving of the same-sized pile (Oestman *et al.*, 2009). Rise time is slower, reducing the probability and severity of injury, and sound energy is distributed over a greater amount of time (Nedwell and Edwards, 2002; Carlson *et al.*, 2005).

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals, and exposure to sound can have deleterious effects. To appropriately assess these potential effects, it is necessary to understand the frequency ranges marine mammals are able to hear. Current data indicate that not all marine mammal species have equal hearing capabilities (e.g., Richardson *et al.*, 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.*

(2007) recommended that marine mammals be divided into functional hearing groups based on measured or estimated hearing ranges on the basis of available behavioral data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. The lower and/or upper frequencies for some of these functional hearing groups have been modified from those designated by Southall *et al.* (2007). The functional groups and the associated frequencies are indicated below (note that these frequency ranges do not necessarily correspond to the range of best hearing, which varies by species):

- Low-frequency cetaceans (mysticetes): Functional hearing is estimated to occur between approximately 7 Hz and 30 kHz (extended from 22 kHz; Watkins, 1986; Au *et al.*, 2006; Lucifredi and Stein, 2007; Ketten and Mountain, 2009; Tubelli *et al.*, 2012);
- Mid-frequency cetaceans (larger toothed whales, beaked whales, and most delphinids): Functional hearing is estimated to occur between approximately 150 Hz and 160 kHz;
- High-frequency cetaceans (porpoises, river dolphins, and members of the genera *Kogia* and *Cephalorhynchus*; now considered to include two members of the genus *Lagenorhynchus* on the basis of recent echolocation data and genetic data [May-Collado and Agnarsson, 2006; Kyhn *et al.* 2009, 2010; Tougaard *et al.* 2010]): Functional hearing is estimated to occur between approximately 200 Hz and 180 kHz; and
- Pinnipeds in water: Functional hearing is estimated to occur between

approximately 75 Hz to 100 kHz for Phocidae (true seals) and between 100 Hz and 40 kHz for Otariidae (eared seals), with the greatest sensitivity between approximately 700 Hz and 20 kHz. The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.*, 2006; Kastelein *et al.*, 2009; Reichmuth *et al.*, 2013).

There are five marine mammal species (two cetacean and three pinniped [two otariid and one phocid] species) with expected potential to co-occur with Navy construction activities. Please refer to Table 1. Of the two cetacean species that may be present, the killer whale is classified as mid-frequency and the gray whale is classified as low-frequency.

Acoustic Effects, Underwater

Potential Effects of Pile Driving Sound—The effects of sounds from pile driving might result in one or more of the following: Temporary or permanent hearing impairment, non-auditory physical or physiological effects, behavioral disturbance, and masking (Richardson *et al.*, 1995; Gordon *et al.*, 2004; Nowacek *et al.*, 2007; Southall *et al.*, 2007). The effects of pile driving on marine mammals are dependent on several factors, including the size, type, and depth of the animal; the depth, intensity, and duration of the pile driving sound; the depth of the water column; the substrate of the habitat; the standoff distance between the pile and the animal; and the sound propagation properties of the environment. Impacts to marine mammals from pile driving activities are expected to result primarily from acoustic pathways. As such, the degree of effect is intrinsically related to the received level and duration of the sound exposure, which are in turn influenced by the distance between the animal and the source. The further away from the source, the less intense the exposure should be. The substrate and depth of the habitat affect the sound propagation properties of the environment. Shallow environments are typically more structurally complex, which leads to rapid sound attenuation. In addition, substrates that are soft (e.g., sand) would absorb or attenuate the sound more readily than hard substrates (e.g., rock) which may reflect the acoustic wave. Soft porous substrates would also likely require less time to drive the pile, and possibly less forceful equipment, which would ultimately

decrease the intensity of the acoustic source.

In the absence of mitigation, impacts to marine species would be expected to result from physiological and behavioral responses to both the type and strength of the acoustic signature (Viada *et al.*, 2008). The type and severity of behavioral impacts are more difficult to define due to limited studies addressing the behavioral effects of impulsive sounds on marine mammals. Potential effects from impulsive sound sources can range in severity from effects such as behavioral disturbance or tactile perception to physical discomfort, slight injury of the internal organs and the auditory system, or mortality (Yelverton *et al.*, 1973).

Hearing Impairment and Other Physical Effects—Marine mammals exposed to high intensity sound repeatedly or for prolonged periods can experience hearing threshold shift (TS), which is the loss of hearing sensitivity at certain frequency ranges (Kastak *et al.*, 1999; Schlundt *et al.*, 2000; Finneran *et al.*, 2002, 2005). TS can be permanent (PTS), in which case the loss of hearing sensitivity is not recoverable, or temporary (TTS), in which case the animal's hearing threshold would recover over time (Southall *et al.*, 2007). Marine mammals depend on acoustic cues for vital biological functions, (e.g., orientation, communication, finding prey, avoiding predators); thus, TTS may result in reduced fitness in survival and reproduction. However, this depends on the frequency and duration of TTS, as well as the biological context in which it occurs. TTS of limited duration, occurring in a frequency range that does not coincide with that used for recognition of important acoustic cues, would have little to no effect on an animal's fitness. Repeated sound exposure that leads to TTS could cause PTS. PTS constitutes injury, but TTS does not (Southall *et al.*, 2007). The following subsections discuss in somewhat more detail the possibilities of TTS, PTS, and non-auditory physical effects.

Temporary Threshold Shift—TTS is the mildest form of hearing impairment that can occur during exposure to a strong sound (Kryter, 1985). While experiencing TTS, the hearing threshold rises, and a sound must be stronger in order to be heard. In terrestrial mammals, TTS can last from minutes or hours to days (in cases of strong TTS). For sound exposures at or somewhat above the TTS threshold, hearing sensitivity in both terrestrial and marine mammals recovers rapidly after exposure to the sound ends. Few data on sound levels and durations necessary

to elicit mild TTS have been obtained for marine mammals, and none of the published data concern TTS elicited by exposure to multiple pulses of sound. Available data on TTS in marine mammals are summarized in Southall *et al.* (2007).

Given the available data, the received level of a single pulse (with no frequency weighting) might need to be approximately 186 dB re 1 $\mu\text{Pa}^2\cdot\text{s}$ (i.e., 186 dB sound exposure level [SEL] or approximately 221–226 dB p-p [peak]) in order to produce brief, mild TTS. Exposure to several strong pulses that each have received levels near 190 dB rms (175–180 dB SEL) might result in cumulative exposure of approximately 186 dB SEL and thus slight TTS in a small odontocete, assuming the TTS threshold is (to a first approximation) a function of the total received pulse energy.

The above TTS information for odontocetes is derived from studies on the bottlenose dolphin (*Tursiops truncatus*) and beluga whale (*Delphinapterus leucas*). There is no published TTS information for other species of cetaceans. However, preliminary evidence from a harbor porpoise exposed to pulsed sound suggests that its TTS threshold may have been lower (Lucke *et al.*, 2009). As summarized above, data that are now available imply that TTS is unlikely to occur unless odontocetes are exposed to pile driving pulses stronger than 180 dB re 1 μPa rms.

Permanent Threshold Shift—When PTS occurs, there is physical damage to the sound receptors in the ear. In severe cases, there can be total or partial deafness, while in other cases the animal has an impaired ability to hear sounds in specific frequency ranges (Kryter, 1985). There is no specific evidence that exposure to pulses of sound can cause PTS in any marine mammal. However, given the possibility that mammals close to a sound source might incur TTS, there has been further speculation about the possibility that some individuals might incur PTS. Single or occasional occurrences of mild TTS are not indicative of permanent auditory damage, but repeated or (in some cases) single exposures to a level well above that causing TTS onset might elicit PTS.

Relationships between TTS and PTS thresholds have not been studied in marine mammals but are assumed to be similar to those in humans and other terrestrial mammals. PTS might occur at a received sound level at least several decibels above that inducing mild TTS if the animal were exposed to strong sound pulses with rapid rise time.

Based on data from terrestrial mammals, a precautionary assumption is that the PTS threshold for impulse sounds (such as pile driving pulses as received close to the source) is at least 6 dB higher than the TTS threshold on a peak-pressure basis and probably greater than 6 dB (Southall *et al.*, 2007). On an SEL basis, Southall *et al.* (2007) estimated that received levels would need to exceed the TTS threshold by at least 15 dB for there to be risk of PTS. Thus, for cetaceans, Southall *et al.* (2007) estimate that the PTS threshold might be an M-weighted SEL (for the sequence of received pulses) of approximately 198 dB re 1 $\mu\text{Pa}^2\text{-s}$ (15 dB higher than the TTS threshold for an impulse). Given the higher level of sound necessary to cause PTS as compared with TTS, it is considerably less likely that PTS could occur.

Measured source levels from impact pile driving can be as high as 214 dB rms. Although no marine mammals have been shown to experience TTS or PTS as a result of being exposed to pile driving activities, captive bottlenose dolphins and beluga whales exhibited changes in behavior when exposed to strong pulsed sounds (Finneran *et al.*, 2000, 2002, 2005). The animals tolerated high received levels of sound before exhibiting aversive behaviors. Experiments on a beluga whale showed that exposure to a single watergun impulse at a received level of 207 kPa (30 psi) p-p, which is equivalent to 228 dB p-p, resulted in a 7 and 6 dB TTS in the beluga whale at 0.4 and 30 kHz, respectively. Thresholds returned to within 2 dB of the pre-exposure level within four minutes of the exposure (Finneran *et al.*, 2002). Although the source level of pile driving from one hammer strike is expected to be much lower than the single watergun impulse cited here, animals being exposed for a prolonged period to repeated hammer strikes could receive more sound exposure in terms of SEL than from the single watergun impulse (estimated at 188 dB re 1 $\mu\text{Pa}^2\text{-s}$) in the aforementioned experiment (Finneran *et al.*, 2002). However, in order for marine mammals to experience TTS or PTS, the animals have to be close enough to be exposed to high intensity sound levels for a prolonged period of time. Based on the best scientific information available, these SPLs are far below the thresholds that could cause TTS or the onset of PTS.

Non-auditory Physiological Effects—Non-auditory physiological effects or injuries that theoretically might occur in marine mammals exposed to strong underwater sound include stress, neurological effects, bubble formation,

resonance effects, and other types of organ or tissue damage (Cox *et al.*, 2006; Southall *et al.*, 2007). Studies examining such effects are limited. In general, little is known about the potential for pile driving to cause auditory impairment or other physical effects in marine mammals. Available data suggest that such effects, if they occur at all, would presumably be limited to short distances from the sound source and to activities that extend over a prolonged period. The available data do not allow identification of a specific exposure level above which non-auditory effects can be expected (Southall *et al.*, 2007) or any meaningful quantitative predictions of the numbers (if any) of marine mammals that might be affected in those ways. Marine mammals that show behavioral avoidance of pile driving, including some odontocetes and some pinnipeds, are especially unlikely to incur auditory impairment or non-auditory physical effects.

Disturbance Reactions

Disturbance includes a variety of effects, including subtle changes in behavior, more conspicuous changes in activities, and displacement. Behavioral responses to sound are highly variable and context-specific and reactions, if any, depend on species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day, and many other factors (Richardson *et al.*, 1995; Wartzok *et al.*, 2003; Southall *et al.*, 2007).

Habituation can occur when an animal's response to a stimulus wanes with repeated exposure, usually in the absence of unpleasant associated events (Wartzok *et al.*, 2003). Animals are most likely to habituate to sounds that are predictable and unvarying. The opposite process is sensitization, when an unpleasant experience leads to subsequent responses, often in the form of avoidance, at a lower level of exposure. Behavioral state may affect the type of response as well. For example, animals that are resting may show greater behavioral change in response to disturbing sound levels than animals that are highly motivated to remain in an area for feeding (Richardson *et al.*, 1995; NRC, 2003; Wartzok *et al.*, 2003).

Controlled experiments with captive marine mammals showed pronounced behavioral reactions, including avoidance of loud sound sources (Ridgway *et al.*, 1997; Finneran *et al.*, 2003). Observed responses of wild marine mammals to loud pulsed sound sources (typically seismic guns or acoustic harassment devices, but also including pile driving) have been varied

but often consist of avoidance behavior or other behavioral changes suggesting discomfort (Morton and Symonds, 2002; Thorson and Reyff, 2006; see also Gordon *et al.*, 2004; Wartzok *et al.*, 2003; Nowacek *et al.*, 2007). Responses to continuous sound, such as vibratory pile installation, have not been documented as well as responses to pulsed sounds.

With both types of pile driving, it is likely that the onset of pile driving could result in temporary, short term changes in an animal's typical behavior and/or avoidance of the affected area. These behavioral changes may include (Richardson *et al.*, 1995): Changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); avoidance of areas where sound sources are located; and/or flight responses (e.g., pinnipeds flushing into water from haul-outs or rookeries). Pinnipeds may increase their haul-out time, possibly to avoid in-water disturbance (Thorson and Reyff, 2006).

The biological significance of many of these behavioral disturbances is difficult to predict, especially if the detected disturbances appear minor. However, the consequences of behavioral modification could be expected to be biologically significant if the change affects growth, survival, or reproduction. Significant behavioral modifications that could potentially lead to effects on growth, survival, or reproduction include:

- Drastic changes in diving/surfacing patterns (such as those thought to cause beaked whale stranding due to exposure to military mid-frequency tactical sonar);
- Habitat abandonment due to loss of desirable acoustic environment; and
- Cessation of feeding or social interaction.

The onset of behavioral disturbance from anthropogenic sound depends on both external factors (characteristics of sound sources and their paths) and the specific characteristics of the receiving animals (hearing, motivation, experience, demography) and is difficult to predict (Southall *et al.*, 2007).

Auditory Masking

Natural and artificial sounds can disrupt behavior by masking, or interfering with, a marine mammal's ability to hear other sounds. Masking occurs when the receipt of a sound is

interfered with by another coincident sound at similar frequencies and at similar or higher levels. Chronic exposure to excessive, though not high-intensity, sound could cause masking at particular frequencies for marine mammals that utilize sound for vital biological functions. Masking can interfere with detection of acoustic signals such as communication calls, echolocation sounds, and environmental sounds important to marine mammals. Therefore, under certain circumstances, marine mammals whose acoustical sensors or environment are being severely masked could also be impaired from maximizing their performance fitness in survival and reproduction. If the coincident (masking) sound were man-made, it could be potentially harassing if it disrupted hearing-related behavior. It is important to distinguish TTS and PTS, which persist after the sound exposure, from masking, which occurs during the sound exposure. Because masking (without resulting in TS) is not associated with abnormal physiological function, it is not considered a physiological effect, but rather a potential behavioral effect.

The frequency range of the potentially masking sound is important in determining any potential behavioral impacts. Because sound generated from in-water pile driving is mostly concentrated at low frequency ranges, it may have less effect on high frequency echolocation sounds made by porpoises. However, lower frequency man-made sounds are more likely to affect detection of communication calls and other potentially important natural sounds such as surf and prey sound. It may also affect communication signals when they occur near the sound band and thus reduce the communication space of animals (e.g., Clark *et al.*, 2009) and cause increased stress levels (e.g., Foote *et al.*, 2004; Holt *et al.*, 2009).

Masking has the potential to impact species at the population or community levels as well as at individual levels. Masking affects both senders and receivers of the signals and can potentially have long-term chronic effects on marine mammal species and populations. Recent research suggests that low frequency ambient sound levels have increased by as much as 20 dB (more than three times in terms of SPL) in the world's ocean from pre-industrial periods, and that most of these increases are from distant shipping (Hildebrand, 2009). All anthropogenic sound sources, such as those from vessel traffic, pile driving, and dredging activities, contribute to the elevated ambient sound levels, thus intensifying masking.

The most intense underwater sounds in the proposed action are those produced by impact pile driving. Given that the energy distribution of pile driving covers a broad frequency spectrum, sound from these sources would likely be within the audible range of marine mammals present in the project area. Impact pile driving activity is relatively short-term, with rapid pulses occurring for approximately fifteen minutes per pile. The probability for impact pile driving resulting from this proposed action masking acoustic signals important to the behavior and survival of marine mammal species is likely to be negligible. Vibratory pile driving is also relatively short-term, with rapid oscillations occurring for approximately one and a half hours per pile. It is possible that vibratory pile driving resulting from this proposed action may mask acoustic signals important to the behavior and survival of marine mammal species, but the short-term duration and limited affected area would result in insignificant impacts from masking. Any masking event that could possibly rise to Level B harassment under the MMPA would occur concurrently within the zones of behavioral harassment already estimated for vibratory and impact pile driving, and which have already been taken into account in the exposure analysis.

Acoustic Effects, Airborne

Marine mammals that occur in the project area could be exposed to airborne sounds associated with pile driving that have the potential to cause harassment, depending on their distance from pile driving activities. Airborne pile driving sound would have less impact on cetaceans than pinnipeds because sound from atmospheric sources does not transmit well underwater (Richardson *et al.*, 1995); thus, airborne sound would only be an issue for pinnipeds either hauled-out or looking with heads above water in the project area. Most likely, airborne sound would cause behavioral responses similar to those discussed above in relation to underwater sound. For instance, anthropogenic sound could cause hauled-out pinnipeds to exhibit changes in their normal behavior, such as reduction in vocalizations, or cause them to temporarily abandon their habitat and move further from the source. Studies by Blackwell *et al.* (2004) and Moulton *et al.* (2005) indicate a tolerance or lack of response to unweighted airborne sounds as high as 112 dB peak and 96 dB rms.

Anticipated Effects on Habitat

The proposed activities at NBKB would not result in permanent impacts to habitats used directly by marine mammals, such as haul-out sites, but may have potential short-term impacts to food sources such as forage fish and salmonids. The proposed activities could also affect acoustic habitat (see masking discussion above), but this is unlikely given the existing conditions at the project site (see previous discussion of acoustic environment under "Description of Sound Sources" above). There are no rookeries or major haul-out sites, no known foraging hotspots, or other ocean bottom structure of significant biological importance to marine mammals present in the marine waters in the vicinity of the project area. Therefore, the main impact issue associated with the proposed activity would be temporarily elevated sound levels and the associated direct effects on marine mammals, as discussed previously in this document. The most likely impact to marine mammal habitat occurs from pile driving effects on likely marine mammal prey (i.e., fish) near NBKB and minor impacts to the immediate substrate during installation and removal of piles during the pier maintenance project.

Pile Driving Effects on Potential Prey

Construction activities would produce both pulsed (i.e., impact pile driving) and continuous (i.e., vibratory pile driving) sounds. Fish react to sounds which are especially strong and/or intermittent low-frequency sounds. Short duration, sharp sounds can cause overt or subtle changes in fish behavior and local distribution. Hastings and Popper (2005) identified several studies that suggest fish may relocate to avoid certain areas of sound energy. Additional studies have documented effects of pile driving on fish, although several are based on studies in support of large, multiyear bridge construction projects (e.g., Scholik and Yan, 2001, 2002; Popper and Hastings, 2009). Sound pulses at received levels of 160 dB may cause subtle changes in fish behavior. SPLs of 180 dB may cause noticeable changes in behavior (Pearson *et al.*, 1992; Skalski *et al.*, 1992). SPLs of sufficient strength have been known to cause injury to fish and fish mortality. The most likely impact to fish from pile driving activities at the project area would be temporary behavioral avoidance of the area. The duration of fish avoidance of this area after pile driving stops is unknown, but a rapid return to normal recruitment, distribution and behavior is anticipated.

In general, impacts to marine mammal prey species are expected to be minor and temporary due to the short timeframe for the project. However, adverse impacts may occur to a few species of fish which may still be present in the project area despite operating in a reduced work window in an attempt to avoid important fish spawning time periods.

Pile Driving Effects on Potential Foraging Habitat

The area likely impacted by the project is relatively small compared to the available habitat in inland waters in the region. Avoidance by potential prey (i.e., fish) of the immediate area due to the temporary loss of this foraging habitat is also possible. The duration of fish avoidance of this area after pile driving stops is unknown, but a rapid return to normal recruitment, distribution and behavior is anticipated. Any behavioral avoidance by fish of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity.

In summary, given the short daily duration of sound associated with individual pile driving events and the relatively small areas being affected, pile driving activities associated with the proposed action are not likely to have a permanent, adverse effect on any fish habitat, or populations of fish species. The area around NBKB, including the adjacent ferry terminal and nearby marinas, is heavily altered with significant levels of industrial and recreational activity, and is unlikely to harbor significant amounts of forage fish. Thus, any impacts to marine mammal habitat are not expected to cause significant or long-term consequences for individual marine mammals or their populations.

Proposed Mitigation

In order to issue an IHA under Section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses.

Measurements from similar pile driving events were coupled with practical spreading loss to estimate zones of influence (ZOI; see "Estimated Take by Incidental Harassment"); these values were used to develop mitigation measures for pile driving activities at

NBKB. The ZOIs effectively represent the mitigation zone that would be established around each pile to prevent Level A harassment to marine mammals, while providing estimates of the areas within which Level B harassment might occur. In addition to the specific measures described later in this section, the Navy would conduct briefings between construction supervisors and crews, marine mammal monitoring team, and Navy staff prior to the start of all pile driving activity, and when new personnel join the work, in order to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures.

Monitoring and Shutdown for Pile Driving

The following measures would apply to the Navy's mitigation through shutdown and disturbance zones:

Shutdown Zone—For all pile driving activities, the Navy will establish a shutdown zone intended to contain the area in which SPLs equal or exceed the 190 dB rms acoustic injury criteria. The purpose of a shutdown zone is to define an area within which shutdown of activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area), thus preventing injury of marine mammals (as described previously under "Potential Effects of the Specified Activity on Marine Mammals", serious injury or death are unlikely outcomes even in the absence of mitigation measures). Modeled radial distances for shutdown zones are shown in Table 5. However, a minimum shutdown zone of 10 m (which is larger than the maximum predicted injury zone) will be established during all pile driving activities, regardless of the estimated zone. Vibratory pile driving activities are not predicted to produce sound exceeding the 190-dB Level A harassment threshold, but these precautionary measures are intended to prevent the already unlikely possibility of physical interaction with construction equipment and to further reduce any possibility of acoustic injury.

Disturbance Zone—Disturbance zones are the areas in which SPLs equal or exceed 160 and 120 dB rms (for impulse and continuous sound, respectively). Disturbance zones provide utility for monitoring conducted for mitigation purposes (i.e., shutdown zone monitoring) by establishing monitoring protocols for areas adjacent to the shutdown zones. Monitoring of disturbance zones enables observers to be aware of and communicate the

presence of marine mammals in the project area but outside the shutdown zone and thus prepare for potential shutdowns of activity. However, the primary purpose of disturbance zone monitoring is for documenting incidents of Level B harassment; disturbance zone monitoring is discussed in greater detail later (see "Proposed Monitoring and Reporting"). Nominal radial distances for disturbance zones are shown in Table 5.

In order to document observed incidences of harassment, monitors record all marine mammal observations, regardless of location. The observer's location, as well as the location of the pile being driven, is known from a GPS. The location of the animal is estimated as a distance from the observer, which is then compared to the location from the pile. It may then be estimated whether the animal was exposed to sound levels constituting incidental harassment on the basis of predicted distances to relevant thresholds in post-processing of observational and acoustic data, and a precise accounting of observed incidences of harassment created. This information may then be used to extrapolate observed takes to reach an approximate understanding of actual total takes.

Monitoring Protocols—Monitoring would be conducted before, during, and after pile driving activities. In addition, observers shall record all incidents of marine mammal occurrence, regardless of distance from activity, and shall document any behavioral reactions in concert with distance from piles being driven. Observations made outside the shutdown zone will not result in shutdown; that pile segment would be completed without cessation, unless the animal approaches or enters the shutdown zone, at which point all pile driving activities would be halted. Monitoring will take place from fifteen minutes prior to initiation through thirty minutes post-completion of pile driving activities. Pile driving activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than thirty minutes. Please see the Monitoring Plan (Appendix C in the Navy's application), developed by the Navy in agreement with NMFS, for full details of the monitoring protocols.

The following additional measures apply to visual monitoring:

(1) Monitoring will be conducted by qualified observers, who will be placed at the best vantage point(s) practicable to monitor for marine mammals and implement shutdown/delay procedures when applicable by calling for the

shutdown to the hammer operator. Qualified observers are trained biologists, with the following minimum qualifications:

- Visual acuity in both eyes (correction is permissible) sufficient for discernment of moving targets at the water's surface with ability to estimate target size and distance; use of binoculars may be necessary to correctly identify the target;
- Advanced education in biological science or related field (undergraduate degree or higher required);
- Experience and ability to conduct field observations and collect data according to assigned protocols (this may include academic experience);
- Experience or training in the field identification of marine mammals, including the identification of behaviors;
- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates and times when in-water construction activities were suspended to avoid potential incidental injury from construction sound of marine mammals observed within a defined shutdown zone; and marine mammal behavior; and
- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

(2) Prior to the start of pile driving activity, the shutdown zone will be monitored for fifteen minutes to ensure that it is clear of marine mammals. Pile driving will only commence once observers have declared the shutdown zone clear of marine mammals; animals will be allowed to remain in the shutdown zone (i.e., must leave of their own volition) and their behavior will be monitored and documented. The shutdown zone may only be declared clear, and pile driving started, when the entire shutdown zone is visible (i.e., when not obscured by dark, rain, fog, etc.). In addition, if such conditions should arise during impact pile driving that is already underway, the activity would be halted.

(3) If a marine mammal approaches or enters the shutdown zone during the course of pile driving operations, activity will be halted and delayed until either the animal has voluntarily left and been visually confirmed beyond the

shutdown zone or fifteen minutes have passed without re-detection of the animal. Monitoring will be conducted throughout the time required to drive a pile.

Special Conditions

The Navy has not requested the authorization of incidental take for killer whales or gray whales (see discussion below in "Estimated Take by Incidental Harassment"). Therefore, shutdown would be implemented in the event that either of these species is observed in the vicinity, prior to entering the defined disturbance zone. As described later in this document, we believe that occurrence of these species during the in-water work window would be uncommon and that the occurrence of an individual or group would likely be highly noticeable and would attract significant attention in local media and with local whale watchers and interested citizens.

Prior to the start of pile driving on any day, the Navy would contact and/or review the latest sightings data from the Orca Network and/or Center for Whale Research to determine the location of the nearest marine mammal sightings. The Orca Sightings Network consists of a list of over 600 residents, scientists, and government agency personnel in the U.S. and Canada, and includes passive acoustic detections. The presence of a killer whale or gray whale in the southern reaches of Puget Sound would be a notable event, drawing public attention and media scrutiny. With this level of coordination in the region of activity, the Navy should be able to effectively receive real-time information on the presence or absence of whales, sufficient to inform the day's activities. Pile driving would not occur if there was the risk of incidental harassment of a species for which incidental take was not authorized.

During vibratory pile removal, four land-based observers will monitor the area; these would be positioned with two at the pier work site, one at the eastern extent of the ZOI in the Manette neighborhood of Bremerton, and one at the southern extent of the ZOI near the Annapolis ferry landing in Port Orchard (please see Figure 1 of Appendix C in the Navy's application). Additionally, one vessel-based observer will travel through the monitoring area, completing an entire loop approximately every thirty minutes. If any killer whales or gray whales are detected, activity would not begin or would shut down.

Timing Restrictions

In the project area, designated timing restrictions exist to avoid in-water work

when salmonids and other spawning forage fish are likely to be present. The in-water work window is June 15–March 1. All in-water construction activities would occur only during daylight hours (sunrise to sunset).

Soft Start

The use of a soft start procedure is believed to provide additional protection to marine mammals by warning or providing a chance to leave the area prior to the hammer operating at full capacity, and typically involves a requirement to initiate sound from the hammer at reduced energy followed by a waiting period. This procedure is repeated two additional times. It is difficult to specify the reduction in energy for any given hammer because of variation across drivers and, for impact hammers, the actual number of strikes at reduced energy will vary because operating the hammer at less than full power results in "bouncing" of the hammer as it strikes the pile, resulting in multiple "strikes." The pier maintenance project will utilize soft start techniques for both impact and vibratory pile driving. We require the Navy to initiate sound from vibratory hammers for fifteen seconds at reduced energy followed by a thirty-second waiting period, with the procedure repeated two additional times. For impact driving, we require an initial set of three strikes from the impact hammer at reduced energy, followed by a thirty-second waiting period, then two subsequent three strike sets. Soft start will be required at the beginning of each day's pile driving work and at any time following a cessation of pile driving of thirty minutes or longer.

We have carefully evaluated the Navy's proposed mitigation measures and considered their effectiveness in past implementation to preliminarily determine whether they are likely to effect 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: (1) The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals, (2) the proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and (3) the practicability of the measure for applicant implementation.

Any mitigation measure(s) we prescribe 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 number (total number or number at biologically important time or location) of individual marine mammals exposed to stimuli expected to result in incidental take (this goal may contribute to 1, above, or to reducing takes by behavioral harassment only).

(3) A reduction in the number (total number or number at biologically important time or location) of times any individual marine mammal would be exposed to stimuli expected to result in incidental take (this goal may contribute to 1, above, or to reducing takes by behavioral harassment only).

(4) A reduction in the intensity of exposure to stimuli expected to result in incidental take (this goal may contribute to 1, above, or to reducing the severity of behavioral harassment only).

(5) Avoidance or minimization of adverse effects to marine mammal habitat, paying particular attention to the prey base, blockage or limitation of passage to or from biologically important areas, permanent destruction of habitat, or temporary 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 Navy's proposed measures, as well as any other potential measures that may be relevant to the specified activity, we have 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 IHA for an activity, Section 101(a)(5)(D) of the MMPA states that NMFS must 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 incidental take authorizations 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.

Any monitoring requirement we prescribe should improve our understanding of one or more of the following:

- Occurrence of marine mammal species in action area (e.g., presence, abundance, distribution, density).
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (e.g., source characterization, propagation, ambient noise); (2) Affected species (e.g., life history, dive patterns); (3) Co-occurrence of marine mammal species with the action; or (4) Biological or behavioral context of exposure (e.g., age, calving or feeding areas).
- Individual responses to acute stressors, or impacts of chronic exposures (behavioral or physiological).
- How anticipated responses to stressors impact either: (1) Long-term fitness and survival of an individual; or (2) Population, species, or stock.
- Effects on marine mammal habitat and resultant impacts to marine mammals.
- Mitigation and monitoring effectiveness.

The Navy submitted a marine mammal monitoring plan as part of the IHA application for year one of this project. It will be carried forward for year two of this project and can be found as Appendix C of the Navy's application, on the Internet at www.nmfs.noaa.gov/pr/permits/incidental.htm.

Acoustic Monitoring

The Navy will implement a sound source level verification study during the specified activities. Data will be collected in order to estimate airborne and underwater source levels for vibratory removal of timber piles and impact driving of concrete piles, with measurements conducted for ten piles of each type. Monitoring will include one underwater and one airborne monitoring position. These exact positions will be determined in the field during consultation with Navy personnel, subject to constraints related to logistics and security requirements. Reporting of measured sound level signals will include the average, minimum, and maximum rms value and frequency spectra for each pile monitored. Please see section 11.4.4 of the Navy's application for details of the Navy's acoustic monitoring plan.

Visual Marine Mammal Observations

The Navy will collect sighting data and behavioral responses to construction for marine mammal species observed in the region of activity during the period of activity. All observers will be trained in marine mammal identification and behaviors and are required to have no other construction-related tasks while conducting monitoring. The Navy will monitor the shutdown zone and disturbance zone before, during, and after pile driving, with observers located at the best practicable vantage points. Based on our requirements, the Navy would implement the following procedures for pile driving:

- MMOs would be located at the best vantage point(s) in order to properly see the entire shutdown zone and as much of the disturbance zone as possible.
- During all observation periods, observers will use binoculars and the naked eye to search continuously for marine mammals.
- If the shutdown zones are obscured by fog or poor lighting conditions, pile driving at that location will not be initiated until that zone is visible. Should such conditions arise while impact driving is underway, the activity would be halted.

- The shutdown and disturbance zones around the pile will be monitored for the presence of marine mammals before, during, and after any pile driving or removal activity.

During vibratory pile removal, four observers would be deployed as described under Proposed Mitigation, including four land-based observers and one-vessel-based observer traversing the extent of the Level B harassment zone. During impact driving, one observer would be positioned at or near the pile to observe the much smaller disturbance zone.

Individuals implementing the monitoring protocol will assess its effectiveness using an adaptive approach. Monitoring biologists will use their best professional judgment throughout implementation and seek improvements to these methods when deemed appropriate. Any modifications to protocol will be coordinated between NMFS and the Navy.

Data Collection

We require that observers use approved data forms. Among other pieces of information, the Navy will record detailed information about any implementation of shutdowns, including the distance of animals to the pile and description of specific actions that ensued and resulting behavior of

the animal, if any. In addition, the Navy will attempt to distinguish between the number of individual animals taken and the number of incidents of take. We require that, at a minimum, the following information be collected on the sighting forms:

- Date and time that monitored activity begins or ends;
- Construction activities occurring during each observation period;
- Weather parameters (e.g., percent cover, visibility);
- Water conditions (e.g., sea state, tide state);
- Species, numbers, and, if possible, sex and age class of marine mammals;
- Description of any observable marine mammal behavior patterns, including bearing and direction of travel and distance from pile driving activity;
- Distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point;
- Description of implementation of mitigation measures (e.g., shutdown or delay).
- Locations of all marine mammal observations; and
- Other human activity in the area.

Reporting

A draft report would be submitted to NMFS within 45 days of the completion of marine mammal monitoring, or sixty days prior to the issuance of any subsequent IHA for this project, whichever comes first. The report will include marine mammal observations pre-activity, during-activity, and post-activity during pile driving days, and will also provide descriptions of any behavioral responses to construction activities by marine mammals and a complete description of all mitigation shutdowns and the results of those actions and an extrapolated total take estimate based on the number of marine mammals observed during the course of construction. A final report must be submitted within thirty days following resolution of comments on the draft report.

Monitoring Results From Previously Authorized Activities

The Navy complied with the mitigation and monitoring required under the previous authorization for this project. Marine mammal monitoring occurred before, during, and after each pile driving event. During the course of these activities, the Navy did not exceed the take levels authorized under the IHA.

In accordance with the 2013 IHA, the Navy submitted a monitoring report (Appendix D of the Navy's application).

The Navy's specified activity in relation to the 2013 IHA included a total of 65 pile driving days; however, only a limited program of test pile driving actually took place. Pile driving occurred on only two days, with a total of only two piles driven (both impact-driven concrete piles). The only species observed was the California sea lion. A total of 24 individuals were observed within the defined Level B harassment zone, but all were hauled-out on port security barrier floats outside of the defined Level B harassment zone for airborne sound. Therefore, no take of marine mammals occurred incidental to project activity under the year one IHA.

Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines "harassment" as: ". . . any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [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 resulting from vibratory and impact pile driving and 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 Level A harassment, serious injury, or mortality is considered discountable. However, it is unlikely that injurious or lethal takes would occur even in the absence of the planned mitigation and monitoring measures.

If a marine mammal responds to a stimulus by changing its behavior (e.g., through relatively minor changes in locomotion direction/speed or vocalization behavior), the response may or may not constitute taking at the individual level, and is unlikely to affect the stock or the species as a whole. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on animals or on the stock or species could potentially be significant (e.g., Lusseau and Bejder, 2007; Weilgart, 2007). Given the many uncertainties in predicting the quantity and types of impacts of sound on marine mammals, it is common practice to estimate how many animals are likely to be present within a particular

distance of a given activity, or exposed to a particular level of sound. This practice potentially overestimates the numbers of marine mammals taken. In addition, it is often difficult to distinguish between the individuals harassed and incidences of harassment. In particular, for stationary activities, it is more likely that some smaller number of individuals may accrue a number of incidences of harassment per individual than for each incidence to accrue to a new individual, especially if those individuals display some degree of residency or site fidelity and the impetus to use the site (e.g., because of foraging opportunities) is stronger than the deterrence presented by the harassing activity.

The project area is not believed to be particularly important habitat for marine mammals, nor is it considered an area frequented by marine mammals, although harbor seals may be present year-round and sea lions are known to haul-out on man-made objects at the NBKB waterfront. Sightings of other species are rare. Therefore, behavioral disturbances that could result from anthropogenic sound associated with these activities are expected to affect only a relatively small number of individual marine mammals, although those effects could be recurring over the life of the project if the same individuals remain in the project vicinity.

The Navy has requested authorization for the incidental taking of small numbers of Steller sea lions, California sea lions, and harbor seals in Sinclair Inlet and nearby waters that may result from pile driving during construction activities associated with the pier maintenance project described previously in this document. In order to estimate the potential incidents of take that may occur incidental to the specified activity, we must first estimate the extent of the sound field that may be produced by the activity and then consider in combination with information about marine mammal density or abundance in the project area. We first provide information on applicable sound thresholds for determining effects to marine mammals before describing the information used in estimating the sound fields, the available marine mammal density or abundance information, and the method of estimating potential incidents of take.

Sound Thresholds

We use generic sound exposure thresholds to determine when an activity that produces sound might result in impacts to a marine mammal such that a take by harassment might occur. To date, no studies have been

conducted that explicitly examine impacts to marine mammals from pile driving sounds or from which empirical sound thresholds have been established. These thresholds (Table 3) are used to estimate when harassment may occur

(i.e., when an animal is exposed to levels equal to or exceeding the relevant criterion) in specific contexts; however, useful contextual information that may inform our assessment of effects is typically lacking and we consider these

thresholds as step functions. NMFS is working to revise these acoustic guidelines; for more information on that process, please visit www.nmfs.noaa.gov/pr/acoustics/guidelines.htm.

TABLE 3—CURRENT ACOUSTIC EXPOSURE CRITERIA

Criterion	Definition	Threshold
Level A harassment (underwater)	Injury (PTS—any level above that which is known to cause TTS).	180 dB (cetaceans)/190 dB (pinnipeds) (rms)
Level B harassment (underwater)	Behavioral disruption	160 dB (impulsive source)/120 dB (continuous source) (rms)
Level B harassment (airborne)	Behavioral disruption	90 dB (harbor seals)/100 dB (other pinnipeds) (unweighted)

Distance to Sound Thresholds

Underwater Sound Propagation

Formula—Pile driving generates underwater noise that can potentially result in disturbance to marine mammals in the project area. Transmission loss (TL) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. The general formula for underwater TL is:

$$TL = B * \log_{10}(R_1/R_2),$$

Where

R_1 = the distance of the modeled SPL from the driven pile, and
 R_2 = the distance from the driven pile of the initial measurement.

This formula neglects loss due to scattering and absorption, which is

assumed to be zero here. The degree to which underwater sound propagates away from a sound source is dependent on a variety of factors, most notably the water bathymetry and presence or absence of reflective or absorptive conditions including in-water structures and sediments. Spherical spreading occurs in a perfectly unobstructed (free-field) environment not limited by depth or water surface, resulting in a 6 dB reduction in sound level for each doubling of distance from the source ($20 * \log[\text{range}]$). Cylindrical spreading occurs in an environment in which sound propagation is bounded by the water surface and sea bottom, resulting in a reduction of 3 dB in sound level for each doubling of distance from the source ($10 * \log[\text{range}]$). A practical spreading value of fifteen is often used under conditions, such as Sinclair Inlet, where water increases with depth as the receiver moves away from the shoreline,

resulting in an expected propagation environment that would lie between spherical and cylindrical spreading loss conditions. Practical spreading loss (4.5 dB reduction in sound level for each doubling of distance) is assumed here.

Underwater Sound—The intensity of pile driving sounds is greatly influenced by factors such as the type of piles, hammers, and the physical environment in which the activity takes place. However, a limited quantity of literature is available for consideration regarding SPLs recorded from pile driving projects similar to the Navy's activity (i.e., impact-driven concrete piles and vibratory pile removal). In order to determine reasonable SPLs and their associated effects on marine mammals that are likely to result from pile driving at NBKB, studies with similar properties to the specified activity were evaluated, and are displayed in Table 4.

TABLE 4—SUMMARY OF PROXY MEASURED UNDERWATER SPLs

Location	Method	Pile size and material	Measured SPLs
Berth 22, Port of Oakland ¹	Impact	24-in concrete	176 dB at 10 m.
Mad River Slough, CA ¹	Vibratory	13-in steel pipe	155 dB at 10 m.
Port Townsend, WA ²	Vibratory (removal)	12-in timber	150 dB at 16 m.

Sources:¹ Caltrans, 2012; ² Laughlin, 2011

We consider the values presented in Table 4 to be representative of SPLs that may be produced by impact driving of concrete piles, vibratory removal of steel piles, and vibratory removal of timber piles, respectively. The value from Berth 22 was selected as representative of the

largest concrete pile size to be installed and may be conservative when smaller concrete piles are driven. The value from Mad River Slough is for vibratory installation and would likely be conservative when applied to vibratory extraction, which would be expected to

produce lower SPLs than vibratory installation of same-sized piles. All calculated distances to and the total area encompassed by the marine mammal sound thresholds are provided in Table 5.

TABLE 5—DISTANCES TO RELEVANT SOUND THRESHOLDS AND AREAS OF ENSONIFICATION, UNDERWATER

Description	Distance to threshold (m) and associated area of ensonification (km ²)			
	190 dB	180 dB	160 dB	120 dB
Concrete piles, impact	1.2, <0.0001	5.4, 0.0001	117, 0.04	n/a

TABLE 5—DISTANCES TO RELEVANT SOUND THRESHOLDS AND AREAS OF ENSONIFICATION, UNDERWATER—Continued

Description	Distance to threshold (m) and associated area of ensonification (km ²)			
	190 dB	180 dB	160 dB	120 dB
Steel piles, vibratory	0	0	n/a	2,154 ² , 7.5
Timber piles, vibratory	0	0	n/a	1,585; 5.0

¹ SPLs used for calculations were: 191 dB for impact driving, 170 dB for vibratory removal of steel piles, and 168 dB for vibratory removal of timber piles.

² Areas presented take into account attenuation and/or shadowing by land. Please see Figures B-1 and B-2 in the Navy's application.

Sinclair Inlet does not represent open water, or free field, conditions. Therefore, sounds would attenuate according to the shoreline topography. Distances shown in Table 5 are estimated for free-field conditions, but areas are calculated per the actual conditions of the action area. See Figures B-1 and B-2 of the Navy's application for a depiction of areas in which each underwater sound threshold is predicted to occur at the project area due to pile driving.

Airborne Sound—Pile driving can generate airborne sound that could

potentially result in disturbance to marine mammals (specifically, pinnipeds) which are hauled out or at the water's surface. As was discussed for underwater sound from pile driving, the intensity of pile driving sounds is greatly influenced by factors such as the type of piles, hammers, and the physical environment in which the activity takes place. As before, measured values from other studies were used as proxy values to determine reasonable airborne SPLs and their associated effects on marine mammals that might result from pile

driving at NBKB. There are no measurements known for unweighted airborne sound from either impact driving of concrete piles or for vibratory driving of timber piles. A spherical spreading loss model (i.e., 6 dB reduction in sound level for each doubling of distance from the source), in which there is a perfectly unobstructed (free-field) environment not limited by depth or water surface, is appropriate for use with airborne sound and was used to estimate the distance to the airborne thresholds.

TABLE 6—SUMMARY OF PROXY MEASURED AIRBORNE SPLS

Location	Method	Pile size and material	Measured SPLs
Test Pile Program, Hood Canal ¹	Impact	24-in steel pipe	89 dB at 15 m.
Wahkiakum Ferry Terminal, WA ²	Vibratory	18-in steel pipe	87.5 dB at 15 m.

Sources: ¹ Illingworth & Rodkin, 2012; ² Laughlin, 2010

Steel piles generally produce louder source levels than do similarly sized concrete or timber piles. Similarly, the value shown here for the larger steel piles (18-in) would likely be louder than

smaller steel piles or timber piles. Therefore, these values will likely overestimate the distances to relevant thresholds. Based on these values and the assumption of spherical spreading

loss, distances to relevant thresholds and associated areas of ensonification are presented in Table 7; these areas are depicted in Figure B-3 of the Navy's application.

TABLE 7—DISTANCES TO RELEVANT SOUND THRESHOLDS AND AREAS OF ENSONIFICATION, AIRBORNE

Group	Distance to threshold (m) and associated area of ensonification (m ²)	
	Impact driving	Vibratory driving
Harbor seals	13, 169	11, 121
Sea lions	5, 25	4, 16

¹ SPLs used for calculations were: 112.5 dB for impact driving and 111 dB for use of a vibratory hammer.

However, because there are no regular haul-outs within such a small area around the site of proposed pile driving activity, we believe that incidents of incidental take resulting solely from airborne sound are unlikely. In particular, the zones for sea lions are within the minimum shutdown zone defined for underwater sound, and the zones for harbor seals are only slightly larger. It is extremely unlikely that any structure would be available as a haul-out opportunity within these zones, or that an animal would haul out in such close proximity to pile driving activity.

There is a remote possibility that an animal could surface in-water, but with head out, within one of the defined zones and thereby be exposed to levels of airborne sound that we associate with harassment, but any such occurrence would likely be accounted for in our estimation of incidental take from underwater sound.

In summary, we generally recognize that pinnipeds occurring within an estimated airborne harassment zone, whether in the water or hauled out, could be exposed to airborne sound that may result in behavioral harassment.

However, any animal exposed to airborne sound above the behavioral harassment threshold is likely to also be exposed to underwater sound above relevant thresholds (which are typically in all cases larger zones than those associated with airborne sound). Thus, the behavioral harassment of these animals is already accounted for in these estimates of potential take. Multiple incidents of exposure to sound above NMFS' thresholds for behavioral harassment are not believed to result in increased behavioral disturbance, in either nature or intensity of disturbance

reaction. Therefore, we do not believe that authorization of incidental take resulting from airborne sound for pinnipeds is warranted, and airborne sound is not discussed further here.

Marine Mammal Densities

For all species, the best scientific information available was considered for use in the marine mammal take assessment calculations. The Navy has developed, with input from regional marine mammal experts, estimates of marine mammal densities in Washington inland waters for the Navy Marine Species Density Database (NMSDD). A technical report (Hanser et al., 2014) describes methodologies and available information used to derive these densities, which are generally based upon the best available information for Washington inland waters, except where specific local abundance information is available.

At NBKB, the Navy began collecting opportunistic observational data of animals hauled-out on the floating security barrier. These surveys began in February 2010 and have been conducted approximately monthly from September 2010 through present (DoN, 2013). In addition, the Washington State Department of Transportation (WSDOT) recently conducted in-water pile driving over the course of multiple work windows as part of the Manette Bridge construction project in the nearby Port Washington Narrows. WSDOT conducted required marine mammal monitoring as part of this project (WSDOT, 2011, 2012; Rand, 2011). Here, we considered NMSDD density information for all five species we believe to have the potential for occurrence in the project area, but determined it most appropriate to use local abundance data for the three pinniped species. Density information is shown in Table 8; see Hanser et al. (2014) for descriptions of how the densities were derived. That document is publicly available on the Internet at <http://nwtteis.com/DocumentsandReferences/NWTTDocuments/SupportingTechnicalDocuments.aspx> (accessed June 20, 2014). See below for discussion of gray whale and killer whale.

Description of Take Calculation

The following assumptions are made when estimating potential incidences of take:

- All marine mammal individuals potentially available are assumed to be present within the relevant area, and thus incidentally taken;

- An individual can only be taken once during a 24-h period;
- There were will be sixty total days of activity; and,
- Exposures to sound levels at or above the relevant thresholds equate to take, as defined by the MMPA.

The estimation of marine mammal takes typically uses the following calculation:

Exposure estimate = (n * ZOI) * days of total activity

Where:

n = density estimate used for each species/season

ZOI = sound threshold ZOI area; the area encompassed by all locations where the SPLs equal or exceed the threshold being evaluated

n * ZOI produces an estimate of the abundance of animals that could be present in the area for exposure, and is rounded to the nearest whole number before multiplying by days of total activity.

The ZOI impact area is estimated using the relevant distances in Table 5, taking into consideration the possible affected area due to topographical constraints of the action area (i.e., radial distances to thresholds are not always reached). When local abundance is the best available information, in lieu of the density-area method described above, we may simply multiply some number of animals (as determined through counts of animals hauled-out) by the number of days of activity, under the assumption that all of those animals will be present and incidentally taken on each day of activity.

There are a number of reasons why estimates of potential incidents of take may be conservative, assuming that available density or abundance estimates and estimated ZOI areas are accurate. We assume, in the absence of information supporting a more refined conclusion, that the output of the calculation represents the number of individuals that may be taken by the specified activity. In fact, in the context of stationary activities such as pile driving and in areas where resident animals may be present, this number more realistically represents the number of incidents of take that may accrue to a smaller number of individuals. While pile driving can occur any day throughout the in-water work window, and the analysis is conducted on a per day basis, only a fraction of that time (typically a matter of hours on any given day) is actually spent pile driving. The potential effectiveness of mitigation measures in reducing the number of takes is typically not quantified in the take estimation process. For these

reasons, these take estimates may be conservative. See Table 8 for total estimated incidents of take.

Harbor Seal—While no harbor seal haul-outs are present in the action area or in the immediate vicinity of NBKB, haul-outs are present elsewhere in Sinclair Inlet and in other nearby waters and harbor seals may haul out on available objects opportunistically.

Marine mammal monitoring conducted during pile driving work on the Manette Bridge showed variable numbers of harbor seals (but generally greater than indicated by the uncorrected NMSDD density of 1.219 animals/km²). During the first year of construction (in-water work window only), an average of 3.7 harbor seals were observed per day of monitoring with a maximum of 59 observed in October 2011 (WSDOT, 2011; Rand, 2011). During the most recent construction period (July–November 2012), an average of eleven harbor seals per monitoring day was observed, though some animals were likely counted multiple times (WSDOT, 2012). Given the potential for similar occurrence of harbor seals in the vicinity of NBKB during the in-water construction period, we determined it appropriate to use this most recent, local abundance information in the take assessment calculation.

California Sea Lion—Similar to harbor seals, it is not likely that use of the NMSDD density value for California sea lions (0.13 animals/km²) would adequately represent their potential occurrence in the project area. California sea lions are commonly observed hauled out on the floating security barrier which is in close proximity to Pier 6; counts from 34 surveys (March 2010–July 2014) showed an average of 45 individuals per survey day (range 0–219; DoN, 2014). These counts represent the best local abundance data available and were used in the take assessment calculation.

Steller Sea Lion—No Steller sea lion haul-outs are present within or near the action area, and Steller sea lions have not been observed during Navy waterfront surveys or during monitoring associated with the Manette Bridge construction project. It is assumed that the possibility exists that a Steller sea lion could occur in the project area, but there is no known attractant in Sinclair Inlet, which is a relatively muddy, industrialized area, and the floating security barrier that California sea lions use as an opportunistic haul-out cannot generally accommodate the larger adult Steller sea lions (juveniles could haul-out on the barrier). Use of the NMSDD density estimate (0.037 animals/km²) results in an estimate of zero exposures,

and there are no existing data to indicate that Steller sea lions would occur more frequently locally. However, as a precaution and to account for the possibility that a Steller sea lion could occur in the project area, we assume that one Steller sea lion could occur per day of activity.

Killer Whale—Transient killer whales are rarely observed in the project area, with records since 2002 showing one group transiting through the area in May 2004 and a subsequent, similar observation in May 2010. No other observations have occurred during Navy surveys or during project monitoring for Manette Bridge. Use of the NMSDD density estimate (0.0024 animals/km²) results in an estimate of zero exposures,

and there are no existing data to indicate that killer whales would occur more frequently locally. Therefore, the Navy has not requested the authorization of incidental take for transient killer whales and we do not propose such authorization. The Navy would not begin activity or would shut down upon report of a killer whale present within or approaching the relevant ZOI.

Gray Whale—Gray whales are rarely observed in the project area, and the majority of in-water work would occur when whales are relatively less likely to occur (i.e., outside of March–May). Since 2002 and during the in-water work window, there are observational records of three whales (all during

winter 2008–09) and a stranding record of a fourth whale (January 2013). No other observations have occurred during Navy surveys or during project monitoring for Manette Bridge. Use of the NMSDD density estimate (0.0005 animals/km²) results in an estimate of zero exposures, and there are no existing data to indicate that gray whales would occur more frequently locally. Therefore, the Navy has not requested the authorization of incidental take for gray whales and we do not propose such authorization. The Navy would not begin activity or would shut down upon report of a gray whale present within or approaching the relevant ZOI.

TABLE 8—CALCULATIONS FOR INCIDENTAL TAKE ESTIMATION

Species	n (animals/km ²) ¹	n * ZOI (vibratory steel pile removal) ²	Abundance ³	Total proposed authorized takes (% of total stock)
California sea lion	0.1266	1	45	2700 (0.9)
Steller sea lion	0.0368	0	1	60 (0.09)
Harbor seal	1.219 ⁴	9	11	660 (4.5)
Killer whale (transient)	0.0024 (fall)	0	n/a	0
Gray whale	0.0005 (winter)	0	n/a	0

¹ Best available species- and season-specific density estimate, with season noted in parentheses where applicable (Hanser *et al.*, 2014).

² Product of density and largest ZOI (7.5 km²) rounded to nearest whole number; presented for reference only.

³ Best abundance numbers multiplied by expected days of activity (60) to produce take estimate.

⁴ Uncorrected density; presented for reference only.

Analyses and Preliminary Determinations

Negligible Impact Analysis

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.” 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, we consider other factors, such as the likely nature of any responses (e.g., intensity, duration), the context of any responses (e.g., critical reproductive time or location, migration), as well as the number and nature of estimated Level A harassment takes, the number of estimated mortalities, and effects on habitat.

Pile driving activities associated with the pier maintenance project, as

outlined previously, have the potential to disturb or displace marine mammals. Specifically, the specified activities may result in take, in the form of Level B harassment (behavioral disturbance) only, from underwater sounds generated from pile driving. Potential takes could occur if individuals of these species are present in the ensonified zone when pile driving is happening.

No injury, serious injury, or mortality is anticipated given the nature of the activity and measures designed to minimize the possibility of injury to marine mammals. The potential for these outcomes is minimized through the construction method and the implementation of the planned mitigation measures. Specifically, piles would be removed via vibratory means—an activity that does not have the potential to cause injury to marine mammals due to the relatively low source levels produced (less than 180 dB) and the lack of potentially injurious source characteristics—and, while impact pile driving produces short, sharp pulses with higher peak levels and much sharper rise time to reach those peaks, only small diameter concrete piles are planned for impact driving. Predicted source levels for such impact driving events are significantly

lower than those typical of impact driving of steel piles and/or larger diameter piles. In addition, implementation of soft start and shutdown zones significantly reduces any possibility of injury. Given sufficient “notice” through use of soft start (for impact driving), marine mammals are expected to move away from a sound source that is annoying prior to its becoming potentially injurious. Environmental conditions in Sinclair Inlet are expected to generally be good, with calm sea states, although Sinclair Inlet waters may be more turbid than those further north in Puget Sound or in Hood Canal. Nevertheless, we expect conditions in Sinclair Inlet would allow a high marine mammal detection capability for the trained observers required, enabling a high rate of success in implementation of shutdowns to avoid injury, serious injury, or mortality. In addition, the topography of Sinclair Inlet should allow for placement of observers sufficient to detect cetaceans, should any occur (see Figure 1 of Appendix C in the Navy’s application).

Effects on individuals that are taken by Level B harassment, on the basis of reports in the literature as well as monitoring from other similar activities,

will likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring) (e.g., Thorson and Reyff, 2006; HDR, Inc., 2012). Most likely, individuals will simply move away from the sound source and be temporarily displaced from the areas of pile driving, although even this reaction has been observed primarily only in association with impact pile driving. The pile driving activities analyzed here are similar to, or less impactful than, numerous other construction activities conducted in San Francisco Bay and in the Puget Sound region, which have taken place with no reported injuries or mortality to marine mammals, and no known long-term adverse consequences from behavioral harassment. Repeated exposures of individuals to levels of sound that may cause Level B harassment are unlikely to result in hearing impairment or to significantly disrupt foraging behavior. Thus, even repeated Level B harassment of some small subset of the overall stock is unlikely to result in any significant realized decrease in viability for the affected individuals, and thus would not result in any adverse impact to the stock as a whole. Level B harassment will be reduced to the level of least practicable impact through use of mitigation measures described herein and, if sound produced by project activities is sufficiently disturbing, animals are likely to simply avoid the area while the activity is occurring.

In summary, this negligible impact analysis is founded on the following factors: (1) The possibility of injury, serious injury, or mortality may reasonably be considered discountable; (2) the anticipated incidences of Level B harassment consist of, at worst, temporary modifications in behavior; (3) the absence of any significant habitat within the project area, including rookeries, significant haul-outs, or known areas or features of special significance for foraging or reproduction; (4) the presumed efficacy of the proposed mitigation measures in reducing the effects of the specified activity to the level of least practicable impact. In addition, these stocks are not listed under the ESA or considered depleted under the MMPA. In combination, we believe that these factors, as well as the available body of evidence from other similar activities, demonstrate that the potential effects of the specified activity will have only short-term effects on individuals. The specified activity is not expected to impact rates of recruitment or survival and will therefore not result in

population-level impacts. 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 monitoring and mitigation measures, we preliminarily find that the total marine mammal take from Navy's pier maintenance activities will have a negligible impact on the affected marine mammal species or stocks.

Small Numbers Analysis

The number of incidences of take proposed for authorization for these stocks would be considered small relative to the relevant stocks or populations (less than one percent for both sea lion stocks and less than five percent for harbor seals; Table 8) even if each estimated taking occurred to a new individual. This is an extremely unlikely scenario as, for pinnipeds in estuarine/inland waters, there is likely to be some overlap in individuals present day-to-day.

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, we preliminarily find that small numbers of marine mammals will be taken relative to the populations of the affected species or stocks.

Impact on Availability of Affected Species for Taking for Subsistence Uses

There are no relevant subsistence uses of marine mammals implicated by this action. Therefore, we have 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)

No marine mammal species listed under the ESA are expected to be affected by these activities. Therefore, we have determined that a section 7 consultation under the ESA is not required.

National Environmental Policy Act (NEPA)

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), as implemented by the regulations published by the Council on Environmental Quality (40 CFR parts 1500 through 1508), the Navy prepared an Environmental Assessment (EA) to consider the direct, indirect and cumulative effects to the human environment resulting from the pier

maintenance project. NMFS made the Navy's EA available to the public for review and comment, in relation to its suitability for adoption by NMFS in order to assess the impacts to the human environment of issuance of an IHA to the Navy. Also in compliance with NEPA and the CEQ regulations, as well as NOAA Administrative Order 216-6, NMFS has reviewed the Navy's EA, determined it to be sufficient, and adopted that EA and signed a Finding of No Significant Impact (FONSI) on November 8, 2013.

We have reviewed the Navy's application for a renewed IHA for ongoing construction activities for 2014-15 and the 2013-14 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 2013 FONSI. The 2013 NEPA documents are available for review at www.nmfs.noaa.gov/pr/permits/incidental.htm.

Proposed Authorization

As a result of these preliminary determinations, we propose to issue an IHA to the Navy for conducting the described pier maintenance activities in Sinclair Inlet, from October 1, 2014 through March 1, 2015, 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 Incidental Harassment Authorization (IHA) is valid from October 1, 2014 through March 1, 2015.

2. This IHA is valid only for pile driving and removal activities associated with the Pier Maintenance Project at Naval Base Kitsap Bangor, Washington.

3. General Conditions

(a) A copy of this IHA must be in the possession of the Navy, its designees, and work crew personnel operating under the authority of this IHA.

(b) The species authorized for taking are the harbor seal (*Phoca vitulina richardii*), California sea lion (*Zalophus californianus*), and Steller sea lion (*Eumetopias jubatus monteriensis*).

(c) The taking, by Level B harassment only, is limited to the species listed in condition 3(b). See Table 1 (attached) for numbers of take authorized.

(d) The taking by injury (Level A harassment), serious injury, or death of any of the species listed in condition 3(b) of the Authorization or any taking of any other species of marine mammal is prohibited and may result in the modification, suspension, or revocation of this IHA.

(e) The Navy shall conduct briefings between construction supervisors and crews, marine mammal monitoring team, acoustic monitoring team, and Navy staff prior to the start of all pile driving activity, and when new personnel join the work, in order to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures.

4. Mitigation Measures

The holder of this Authorization is required to implement the following mitigation measures:

(a) For all pile driving, the Navy shall implement a minimum shutdown zone of 10 m radius around the pile. If a marine mammal comes within or approaches the shutdown zone, such operations shall cease.

(b) The Navy shall establish monitoring locations as described below. Please also refer to the Marine Mammal Monitoring Plan (Monitoring Plan; attached).

i. For all vibratory pile removal activities, a minimum of four shore-based observers shall be deployed. Two observers shall be located at the pier work site, with one positioned to achieve optimal monitoring of the shutdown zone and the second positioned to achieve optimal monitoring of surrounding waters of Sinclair Inlet. The two additional observers shall be deployed for optimal monitoring of the further extent of the estimated disturbance zone, with one at the eastern extent in the Manette neighborhood of Bremerton, and one at the southern extent near the Annapolis ferry landing in Port Orchard.

ii. For all vibratory pile removal activities, a minimum of one vessel-based observer shall be deployed and shall conduct regular transits through the estimated disturbance zone for the duration of the activity.

iii. For all impact pile driving activities, a minimum of one shore-based observer shall be located at the pier work site.

iv. These observers shall record all observations of marine mammals, regardless of distance from the pile being driven, as well as behavior and potential behavioral reactions of the

animals. If any killer whales or gray whales are detected, activity must not begin or must shut down.

v. All observers shall be equipped for communication of marine mammal observations amongst themselves and to other relevant personnel (e.g., those necessary to effect activity delay or shutdown).

(c) Prior to the start of pile driving on any day, the Navy shall take measures to ensure that no species for which incidental take is not authorized are located within the vicinity of the action area, to include the following:

i. Observers shall scan the floating security barrier to ensure that no Steller sea lions are present.

ii. The Navy shall contact and/or review the latest sightings data from the Orca Network and/or Center for Whale Research, including passive acoustic detections, to determine the location of the nearest marine mammal sightings.

(d) Monitoring shall take place from fifteen minutes prior to initiation of pile driving activity through thirty minutes post-completion of pile driving activity. Pre-activity monitoring shall be conducted for fifteen minutes to ensure that the shutdown zone is clear of marine mammals, and pile driving may commence when observers have declared the shutdown zone clear of marine mammals. In the event of a delay or shutdown of activity resulting from marine mammals in the shutdown zone, animals shall be allowed to remain in the shutdown zone (i.e., must leave of their own volition) and their behavior shall be monitored and documented. Monitoring shall occur throughout the time required to drive a pile. The shutdown zone must be determined to be clear during periods of good visibility (i.e., the entire shutdown zone and surrounding waters must be visible to the naked eye).

(e) If a marine mammal approaches or enters the shutdown zone, all pile driving activities at that location shall be halted. If pile driving is halted or delayed due to the presence of a marine mammal, the activity may not commence or resume until either the animal has voluntarily left and been visually confirmed beyond the shutdown zone or fifteen minutes have passed without re-detection of the animal.

(f) Monitoring shall be conducted by qualified observers, as described in the Monitoring Plan. Trained observers shall be placed from the best vantage point(s) practicable to monitor for marine mammals and implement shutdown or delay procedures when applicable through communication with the equipment operator.

(g) The Navy shall use soft start techniques recommended by NMFS for vibratory and impact pile driving. Soft start for vibratory drivers requires contractors to initiate sound for fifteen seconds at reduced energy followed by a thirty-second waiting period. This procedure is repeated two additional times. Soft start for impact drivers requires contractors to provide an initial set of strikes at reduced energy, followed by a thirty-second waiting period, then two subsequent reduced energy strike sets. Soft start shall be implemented at the start of each day's pile driving and at any time following cessation of pile driving for a period of thirty minutes or longer. Soft start for impact drivers must be implemented at any time following cessation of impact driving for a period of thirty minutes or longer.

(h) Pile driving shall only be conducted during daylight hours.

5. Monitoring

The holder of this Authorization is required to conduct marine mammal monitoring during pile driving activity. Marine mammal monitoring and reporting shall be conducted in accordance with the Monitoring Plan.

(a) The Navy shall collect sighting data and behavioral responses to pile driving for marine mammal species observed in the region of activity during the period of activity. All observers shall be trained in marine mammal identification and behaviors, and shall have no other construction-related tasks while conducting monitoring.

(b) For all marine mammal monitoring, the information shall be recorded as described in the Monitoring Plan.

(c) The Navy shall conduct acoustic monitoring sufficient to measure underwater and airborne source levels for vibratory removal of timber piles and impact driving of concrete piles. Minimum requirements include:

i. Measurements shall be taken for a minimum of ten piles of each type.

ii. Each hydrophone (underwater) and microphone (airborne) shall be calibrated prior to the beginning of the project and shall be checked at the beginning of each day of monitoring activity.

iii. Environmental data shall be collected including but not limited to: Wind speed and direction, wave height, water depth, precipitation, and type and location of in-water construction activities, as well other factors that could contribute to influencing the airborne and underwater sound levels measured (e.g. aircraft, boats).

iv. The construction contractor shall supply the Navy and monitoring

personnel with an estimate of the substrate condition, hammer model and size, hammer energy settings and any changes to those settings during the piles being monitored.

v. Post-analysis of data shall include the average, minimum, and maximum rms values and frequency spectra for each pile monitored. If equipment used is able to accommodate such a requirement, average, minimum, and maximum peak values shall also be provided.

6. Reporting

The holder of this Authorization is required to:

(a) Submit a draft report on all monitoring conducted under the IHA within 45 days of the completion of marine mammal and acoustic monitoring, or sixty days prior to the issuance of any subsequent IHA for this project, whichever comes first. A final report shall be prepared and submitted within thirty days following resolution of comments on the draft report from NMFS. This report must contain the informational elements described in the Monitoring Plan, at minimum (see attached), and shall also include:

i. Detailed information about any implementation of shutdowns, including the distance of animals to the pile and description of specific actions that ensued and resulting behavior of the animal, if any.

ii. Description of attempts to distinguish between the number of individual animals taken and the number of incidences of take, such as ability to track groups or individuals.

iii. A refined take estimate based on the number of marine mammals observed during the course of construction activities.

iv. Results of acoustic monitoring, including the information described in condition 5(c) of this authorization.

(b) Reporting injured or dead marine mammals:

i. In the unanticipated 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, Navy shall immediately cease the specified activities and report the incident to the Office of Protected Resources (301-427-8425), NMFS, and the West Coast Regional Stranding Coordinator (206-526-6550), NMFS. The report must include the following information:

A. Time and date of the incident;

B. Description of the incident;

C. Environmental conditions (e.g., wind speed and direction, Beaufort sea state, cloud cover, and visibility);

D. Description of all marine mammal observations in the 24 hours preceding the incident;

E. Species identification or

description of the animal(s) involved;

F. Fate of the animal(s); and

G. 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 Navy to determine what measures are necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Navy may not resume their activities until notified by NMFS.

i. In the event that Navy discovers an injured or dead marine mammal, and the lead observer determines 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), Navy shall immediately report the incident to the Office of Protected Resources, NMFS, and the West Coast Regional Stranding Coordinator, NMFS.

The report must include the same information identified in 6(b)(i) of this IHA. Activities may continue while NMFS reviews the circumstances of the incident. NMFS will work with Navy to determine whether additional mitigation measures or modifications to the activities are appropriate.

ii. In the event that Navy discovers an injured or dead marine mammal, and the lead observer determines 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, scavenger damage), Navy shall report the incident to the Office of Protected Resources, NMFS, and the West Coast Regional Stranding Coordinator, NMFS, within 24 hours of the discovery. Navy shall provide photographs or video footage or other documentation of the stranded animal sighting to NMFS.

7. This Authorization may be modified, suspended or withdrawn if the holder fails to abide by the conditions prescribed herein, or if the authorized taking is having more than a negligible impact on the species or stock of affected marine mammals.

Request for Public Comments

We request comment on our analysis, the draft authorization, and any other aspect of this Notice of Proposed IHA for Navy's pier maintenance activities. Please include with your comments any supporting data or literature citations to help inform our final decision on Navy's request for an MMPA authorization.

Dated: August 1, 2014.

Donna S. Wieting,

*Director, Office of Protected Resources,
National Marine Fisheries Service.*

[FR Doc. 2014-18552 Filed 8-5-14; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF DEFENSE

Office of the Secretary

Renewal of Department of Defense Federal Advisory Committees

AGENCY: DoD.

ACTION: Renewal of Federal Advisory Committee.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that it is renewing the charter for the Advisory Committee on Arlington National Cemetery ("the Committee").

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703-692-5952.

SUPPLEMENTARY INFORMATION: This committee's charter is being renewed pursuant to 10 U.S.C. 4723 and under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C. Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b) ("the Sunshine Act"), and 41 CFR 102-3.50(d).

The Committee is a non-discretionary Federal advisory committee that shall make periodic reports and recommendations to the Secretary of the Army with respect to the administration of Arlington National Cemetery, the erection of memorials at the cemetery, and master planning for the cemetery. Any and all advice and recommendations shall also be forwarded to the Secretary of Defense or the Deputy Secretary of Defense.

The Secretary of the Army may act upon the Committee's advice and recommendations. Not later than 90 days after receiving a report or recommendations from the Committee, the Secretary of the Army shall submit the report or recommendations to the congressional defense committees and the Committees on Veterans' Affairs of the Senate and House of Representatives and include such comments and recommendations as the Secretary of the Army considers appropriate.

The Department of Defense (DoD), through the Department of the Army, shall provide support deemed necessary for the Committee's performance of its functions and shall ensure compliance with the requirements of the FACA, the

Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended) ("the Sunshine Act"), governing Federal statutes and regulations, and established DoD policies and procedures.

The Committee shall be comprised of no more than nine members, who are eminent authorities in their respective fields of interest or expertise, specifically bereavement practices and administrative oversight, the erection of memorials, and master planning for extending the life of the cemetery, including one member nominated by the Secretary of Veterans Affairs, one member nominated by the Secretary of the American Battle Monuments Commission, and no more than seven members nominated by the Secretary of the Army.

Committee members shall serve a term of service of one-to-four years, but no member may serve more than two consecutive terms of service without approval from the Secretary of Defense or the Deputy Secretary of Defense.

Committee members appointed by the Secretary of Defense or the Deputy Secretary of Defense, who are not full-time Federal officers or employees, shall be appointed as experts or consultants pursuant to 5 U.S.C. 3109, to serve as special government employee (SGE) members. Those individuals serving on the Committee who are full-time or permanent part-time Federal employees shall be appointed to serve as regular government employee (RGE) members pursuant to 41 CFR 102–3.130(a).

The Secretary of the Army will designate, for Secretary of Defense or Deputy Secretary of Defense approval, the Committee's chair from the total approved membership. With the exception of reimbursement for official Committee-related travel and per diem, Committee members shall serve without compensation.

DoD, when necessary and consistent with the Committee's mission and DoD policies and procedures, may establish subcommittees, task forces, or working groups to support the Committee. Establishment of subcommittees will be based upon a written determination, to include terms of reference, by the Secretary of Defense, the Deputy Secretary of Defense, or the Secretary of the Army, as the DoD Sponsor.

Such subcommittees shall not work independently of the Committee and shall report all of their recommendations and advice solely to the Committee for full and open deliberation and discussion. Subcommittees, task forces, or working groups have no authority to make decisions and recommendations, verbally or in writing, on behalf of the

Committee. No subcommittee or any of its members can update or report, verbally or in writing, on behalf of the Committee, directly to the DoD or any Federal officer or employee.

The Secretary of Defense or the Deputy Secretary of Defense shall appoint subcommittee members to a term of service of one-to-four years, even if the member in question is a member of the Committee. Subcommittee members shall not serve more than two consecutive terms of service unless authorized by the Secretary of Defense or the Deputy Secretary of Defense. Subcommittee members, if not full-time or permanent part-time Federal employees, will be appointed as experts or consultants, pursuant to 5 U.S.C. 3109, to serve as SGE members, whose appointments must be renewed on an annual basis. Those individuals who are full-time or permanent part-time Federal employees shall be appointed to serve as RGE members, pursuant to 41 CFR 102–3.130(a). With the exception of reimbursement of official travel and per diem related to the Committee or its subcommittees, subcommittee members shall serve without compensation.

All subcommittees operate under the provisions of FACA, the Sunshine Act, governing Federal statutes and regulations, and established DoD policies and procedures.

The Committee has three permanent subcommittees. Each subcommittee member should have extensive professional experience in at least one of the following areas of operation and management of cemeteries: Bereavement practices; erection of memorials and master planning; plans and strategies for addressing long-term governance challenges; and resource planning and allocation.

a. The Honor Subcommittee shall be comprised of no more than nine members. The primary focus of this subcommittee is to review and provide recommendations to the Committee regarding methods to address the long-term future of the Arlington National Cemetery, including how best to extend the active burials and what Arlington National Cemetery should focus on once all available space has been used. The estimated number of subcommittee meetings is up to nine per year.

b. The Remember Subcommittee shall be comprised of no more than nine members. The primary focus of this subcommittee is to review and provide recommendations to the Committee on an independent assessment of methods to maintain the Tomb of the Unknown Soldier Monument, including the cracks in the large marble sarcophagus, the

adjacent marble slabs, and the potential replacement marble stone for the sarcophagus already gifted to the Army. The estimated number of subcommittee meetings is up to nine per year.

c. The Explore Subcommittee shall be comprised of no more than nine members. The primary focus of this subcommittee is to review and provide recommendations to the Committee on efforts to preserve the historic essence of Arlington National Cemetery and the development of an interactive means to share the Cemetery's unique history with the nation and the world, including an independent assessment of methods to address the issues dealing with capturing and conveying the Army national cemeteries' history, including examining Arlington National Cemetery Section 60 gravesite mementos and improving the quality of visitors' experiences now and for generations to come. The estimated number of subcommittee meetings is up to nine per year.

The estimated number of Committee meetings is four per year.

The Committee's Designated Federal Officer (DFO) shall be a full-time or permanent part-time DoD employee and shall be appointed in accordance with established DoD policies and procedures.

The Committee's DFO, pursuant to DoD policy, shall be a full-time or permanent part-time DoD employee, and shall be appointed in accordance with established DoD policies and procedures.

The Committee's DFO is required to be in attendance at all meetings of the Committee and any subcommittees for the entire duration of each and every meeting; however, in the absence of the DFO, a properly approved Alternate DFO shall attend the entire duration of all of the meetings of the Committee and its subcommittees.

The DFO, or the Alternate DFO, shall call all meetings of the Committee and its subcommittees; prepare and approve all meeting agendas; and adjourn any meeting when the DFO, or the Alternate DFO, determines adjournment to be in the public interest or required by governing regulations or DoD policies and procedures.

Pursuant to 41 CFR 102–3.105(j) and 102–3.140, the public or interested organizations may submit written statements to Advisory Committee on Arlington National Cemetery membership about the Committee's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of Advisory

Committee on Arlington National Cemetery.

All written statements shall be submitted to the DFO for the Advisory Committee on Arlington National Cemetery, and this individual will ensure that the written statements are provided to the membership for their consideration. Contact information for the Advisory Committee on Arlington National Cemetery DFO can be obtained from the GSA's FACA Database—<http://www.facadatabase.gov/>.

The DFO, pursuant to 41 CFR 102–3.150, will announce planned meetings of the Advisory Committee on Arlington National Cemetery. The DFO, at that time, may provide additional guidance on the submission of written statements that are in response to the stated agenda for the planned meeting in question.

Dated: July 31, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2014–18504 Filed 8–5–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2014–0029]

Proposed Collection; Comment Request

AGENCY: Office of the Deputy Chief of Staff, G–1 Army Resiliency Directorate, SHARP, DOD.

ACTION: Notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the Office of the Deputy Chief of Staff, G–1 Army Resiliency Directorate, DoD, SHARP announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by October 6, 2014.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at <http://www.regulations.gov> for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Office of the Deputy Chief of Staff, G–1 Army Resiliency Directorate, DoD, SHARP, ATTN: Robert Mitchell, Arlington, VA 22202, or call G–1 Army Resiliency Directorate, DoD, SHARP, at 1–855–666–0890.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB

Number: Sexual Assault Response Coordinators (SARC); DD Form 2910; OMB Control Number 0702–XXXX.

Needs and Uses: The information collection requirement is necessary to facilitate the reporting requirements found in 10 U.S.C 3013, Sexual Assault Prevention and Response Program Procedures. Data is collected via a web based case reporting tool (SHARP ICRS) that collects relevant harassment data and maintains relevant assault data regarding the lifecycle of sexual harassment and assault cases for cases involving victims and/or alleged offenders who are members of the Army (either the victim and/or alleged offender(s) must be a uniformed member of the Army Forces, and/or DoD Civilian, and/or DoD Contractor personnel, and either the victim and/or alleged offender(s) must serve or accompany our armed forces as integral parts of the unified mission). Data is

used to conduct case and business management and aggregate data is used to meet congressional reporting requirements.

Affected Public: Individuals or Households.

Annual Burden Hours: 2,400 hours.

Number of Respondents: 2,400.

Responses per Respondent: 1.

Average Burden per Response: 60 minutes.

Frequency: On occasion.

Data is collected by trained Victim Advocates (VAs) and/or Sexual Assault Response Coordinators (SARCs) who have completed the NOVA credentialing process, including eighty hour training. DD Form 2910 is used for initial data collection and data is then input into to SHARP ICRS (harassment) or DSAID (assault).

Dated: August 1, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2014–18546 Filed 8–5–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID USA–2014–0007]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by September 5, 2014.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB

Number: Defense Biometric Identification Records System (ABIS); OMB Control Number 0702–XXXX.

Type of Request: New Collection.

Number of Respondents: 11,568,220.

Responses per Respondent: 1.

Annual Responses: 11,568,220.

Average Burden per Response: 5 minutes.

Annual Burden Hours: 964,018.

Needs and Uses: The information collection requirement for the Defense Biometric Identification Records System (IT System named DoD Automated Biometric Identification System (ABIS)/ Biometric Enabling Capability (BEC)) is necessary to support the DoD, FBI, DHS,

other government agencies, and approved international partners for intelligence, force protection, national security, and law enforcement purposes.

Affected Public: Federal Government, Individuals or Households

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Sehra.

Written comments and recommendations on the proposed information collection should be sent to Ms. Jasmeet Sehra at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket number and title, by the following method:

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

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD Information Management Division, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350-3100.

Dated: August 1, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2014-18581 Filed 8-5-14; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Policy and Procedural Guidance for Processing Requests To Alter U.S. Army Corps of Engineers Civil Works Projects

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

ACTION: Notice.

SUMMARY: The U.S. Army Corps of Engineers (USACE) has issued an Engineer Circular to provide guidance related to how USACE will process

requests by others to alter a USACE civil works project. This notice announces the availability of that guidance.

ADDRESSES: Headquarters, USACE, Engineering and Construction Division, 441 G Street NW., Washington, DC 20314-1000.

FOR FURTHER INFORMATION CONTACT: Ms. Tammy Conforti, Levee Safety Program Manager, Headquarters, USACE, at 202-761-4649.

SUPPLEMENTARY INFORMATION: Section 14 of the Rivers and Harbors Appropriations Act of 1899, as amended, codified in 33 U.S.C. 408 (Section 408) authorizes the Secretary of the Army, on the recommendation of the Chief of Engineers of the U.S. Army Corps of Engineers (USACE), to grant permission for the alteration, occupation, or use of a federally authorized project upon a determination by the Secretary that the activity will not be injurious to the public interest and will not impair the usefulness of the project. USACE has issued Engineer Circular (EC) 1165-2-216, titled Policy and Procedural Guidance for Processing Requests to Alter U.S. Army Corps of Engineers Civil Works Projects Pursuant to 33 U.S.C. 408, to provide guidance related to how USACE will process requests by others to alter a USACE civil works project.

The intent of EC 1165-2-216 is to provide procedures that are scalable and commensurate to the proposed alternation. The EC contains procedural information on environmental compliance; review and approval requirements; and post-approval requirements. The EC applies only to alterations within the lands and real property interests identified for the USACE civil works project. For USACE civil works projects with non-federal sponsors, the EC recognizes their role by requiring direct engagement and/or concurrence on proposed alterations. The appendices of the EC contain supplemental information for proposed alterations for dams, hydropower facilities, levee systems, channel projects, and navigation features.

For more information on the Section 408 process and to view EC 1165-2-216, please visit the USACE Civil Works Web site at <http://www.usace.army.mil/Missions/CivilWorks>. EC 1165-2-216 can also be found on the USACE publication Web site at <http://www.publications.usace.army.mil/>.

Dated: July 31, 2014.

James C. Dalton,

Chief, Engineering and Construction, Directorate of Civil Works.

[FR Doc. 2014-18593 Filed 8-5-14; 8:45 am]

BILLING CODE 3720-58-P

DEPARTMENT OF EDUCATION

[Docket No. ED-2014-ICCD-0115]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; National Assessment of Educational Progress (NAEP) 2015 Wave 3—ECLS-K:2011 Link and Computer Familiarity Study

AGENCY: Institute of Education Sciences/ National Center for Education Statistics (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before September 5, 2014.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting Docket ID number ED-2014-ICCD-0115 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at ICDocketMgr@ed.gov. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will ONLY accept comments during the comment period in this mailbox when the regulations.gov site is not available.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Mailstop L-OM-2-2E319, Room 2E103, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Kashka Kubzdela, 202-502-7411.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the

Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: National Assessment of Educational Progress (NAEP) 2015 Wave 3—ECLS-K:2011 Link and Computer Familiarity Study.

OMB Control Number: 1850-0790.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Individuals or households.

Total Estimated Number of Annual Responses: 19,600.

Total Estimated Number of Annual Burden Hours: 4,267.

Abstract: The National Assessment of Educational Progress (NAEP) is a federally authorized survey of student achievement at grades 4, 8, and 12 in various subject areas, such as mathematics, reading, writing, science, U.S. history, civics, geography, economics, and the arts. In the current legislation that reauthorized NAEP (20 U.S.C. 9622), Congress again mandated the collection of national education survey data through a national assessment program. The 2015 main NAEP Wave 3 contains the descriptions, burden, and questionnaires for two special studies: NAEP—Early Childhood Longitudinal Study, Kindergarten Class of 2010–11 (ECLS-K:2011) Link, and Computer Familiarity Study. Both of these special studies include the administration of an additional student questionnaire to a sub-sample of students participating in the 2015 main NAEP administration.

Dated: August 1, 2014.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2014-18555 Filed 8-5-14; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

Final Waiver and Extension of the Project Period; Striving Readers Comprehensive Literacy Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Final waiver and extension of the project period.

[Catalog of Federal Domestic Assistance (CFDA) Number: 84.371C.]

SUMMARY: For the Montana Department of Education's 36-month grant project funded in fiscal year (FY) 2011, under the Striving Readers Comprehensive Literacy program (SRCL), the Secretary waives the requirements that generally prohibit project period extensions involving the obligation of additional Federal funds. The Secretary also extends the current Montana SCRL project period for an additional 24 months.

DATES: This final waiver and extension of the project period are effective August 6, 2014.

FOR FURTHER INFORMATION CONTACT:

Rosemary Fennell, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E228, Washington, DC 20202-5970. Telephone: (202) 401-2425 or by email: rosemary.fennell@ed.gov.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

SUPPLEMENTARY INFORMATION: On May 20, 2014, we published a notice in the **Federal Register** (79 FR 28917) (May 2014 proposed waiver) proposing an extension of a project period and a waiver of the requirement of 34 CFR 75.261(a) and (c)(2), which restricts project period extensions involving the obligation of additional Federal funds, as it applies to the Montana Department of Education's project funded under the FY 2011 SRCL competition. The Secretary also proposed to extend this grantee's project period for an additional 24 months.

Public Comment

In the May 2014 proposed waiver, the Secretary invited comments on the proposed waiver and extension of the project period. We received 21 comments in response.

Analysis of Comments and Changes

Comment: The 21 commenters who addressed the proposed waiver and extension supported it, discussed the accomplishments of the current SRCL

grantee and benefits of the program, and stated that an extension of the project period would allow the grantee to continue its work and expand on its accomplishments. We did not receive any negative comments regarding the proposed waiver and extension of the project period.

Response: We agree with the commenters that extending the current SCRL grant period for one grantee, the Montana Department of Education and, therefore allowing this grantee to request a continuation award, would enable it to continue to work toward accomplishing its goals and objectives stated in its approved 2011 SCRL grant application.

Change: None.

Background

In FY 2010, Congress appropriated \$200 million to support establishment of a comprehensive literacy development and education program through the Consolidated Appropriations Act (Pub. L. 111-117) under section 1502 of the Elementary and Secondary Education Act of 1965, as amended (ESEA). The purpose of SRCL is to advance literacy skills—including pre-literacy skills, reading, and writing—for students from birth through grade 12, including limited-English-proficient students and students with disabilities. Section 1502 of the ESEA provides the authority for demonstration programs, like SCRL, that show promise of enabling children to meet challenging academic content and achievement standards. In FY 2010, the U.S. Department of Education (the Department) awarded \$10 million in formula grants to 46 States, the District of Columbia, and the Commonwealth of Puerto Rico to establish or support State Literacy Teams with expertise in literacy development and education for children from birth to grade 12 to assist the States in developing a comprehensive literacy plan.

The Department also used FY 2010 funds to award set-aside grants to the Bureau of Indian Education and four Outlying Areas, and to award discretionary grants to six State educational agencies (SEAs) to create comprehensive literacy programs to advance literacy skills—including pre-literacy skills, reading, and writing—for students from birth through grade 12, including limited-English-proficient students and students with disabilities. The Department announced this discretionary grant competition in a notice inviting applications that was published in the **Federal Register** on March 10, 2011 (76 FR 13143) (March 2011 NIA). The grants awarded under

the FY 2011 competition were for a project period of up to five years. The Department indicated in the March 2011 NIA that it planned to make continuation awards in accordance with section 75.253 of the Education Department's General Administrative Regulations (EDGAR) (34 CFR 75.253), depending on the availability of funds.

Five of the six SEA grantees funded under the FY 2011 grant competition submitted a budget for all five years of the grant period. One grantee, the Montana Department of Education, submitted a budget request for only three years, believing that it could request funding for years four and five after receiving a grant award. On March 25, 2014, the Montana Department of Education, Office of Public Instruction, requested to extend its project period for an additional two years.

As outlined in the May 2014 proposed waiver, the FY 2014 appropriation contained sufficient funding to continue Montana's grant. The appropriation for SCRL included \$158 million, an increase of approximately \$6 million over the FY 2013 funding level. The Department does not plan to conduct a new competition in FY 2014, as there are insufficient funds both to provide continuation grants and fund new grantees.

We believe it best serves the interests of the Department and the public to ensure that the full cohort of grantees, including Montana, has the opportunity to complete a full five-year program, as originally intended in the March 2011 NIA. Providing Montana an opportunity for an additional two years of funding, and in turn an additional two years of data on implementation, is consistent with the underlying purpose of the SCRL program funded under the Section 1502 demonstration authority: To provide data on the results of promising literacy practices implemented under the SCRL program.

Additionally, the Montana Department of Education's SCRL project is at a critical point; the State is working with participating local education agencies (LEA) to fully implement the State Literacy Plan, and to implement sustainability efforts and activities. The Montana SCRL Implementation Team continues its work to assess and evaluate the effectiveness of the implementation of the State Literacy Plan, and continues to identify and provide the support and resources necessary to ensure processes and systems created through the SCRL program are sustainable. The Montana Department of Education has used data-driven decisions, through its evaluation and assessment activities, to make improvements to the SCRL program

across 10 LEAs and 32 schools. Without an extension of the project period to allow for the work that will lead to sustainability and full implementation of the State Literacy Plan, the SCRL program may cease in some LEAs and be greatly curtailed in others.

For these reasons, the Secretary waives the requirements in 34 CFR 75.261(a) and (c)(2) of EDGAR that generally prohibit project period extensions involving the obligation of additional Federal funds. The Secretary also extends the current Montana SCRL project period for an additional 24 months. This two-year extension of the project period will ensure seamless program delivery to the sub-grantees awarded under the Montana Department of Education SCRL grant award, as well as data on project implementation.

We will use the process stated in the March 2011 NIA and the regulations in 34 CFR 75.253 to make continuation awards based on information that each grantee provides, indicating that each grantee is making substantial progress performing its SCRL grant activities and is showing improvement against baseline data on specific indicators listed in the March 2011 NIA.

Any activities to be carried out during the remaining continuation years of the SCRL award must be consistent with, or be a logical extension of, the scope, goals, and objectives of each grantee's application as approved in the FY 2011 SCRL competition. With this final waiver and extension of the project period, the project period for the Montana SCRL grantee will be extended through September 30, 2016, which is the same ending date as the ending date for the other SCRL grantees' project periods.

Regulatory Flexibility Act Certification

The Secretary certifies that the waiver and extension of the project period will not have a significant economic impact on a substantial number of small entities. The entities that will be affected by this waiver and extension are the current SCRL grantees receiving Federal funds.

The Secretary certifies that the waiver and extension will not have a significant economic impact on these entities because minimal compliance costs are imposed by extending a single project already in existence, and the activities required to support the additional years of funding will not impose additional regulatory burdens or require unnecessary Federal supervision.

Paperwork Reduction Act of 1995

The final extension of project period and waiver do not contain any information collection requirements.

Intergovernmental Review

This program is subject to Executive Order 12372 and the regulations in 34 CFR parts 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides notification of our specific plans and actions for this program.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: www.gpo.gov/fdsys. At this site you can view this document, as well as all other documents of the Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit the search to documents published by the Department.

Program Authority: Consolidated Appropriations Act, 2010 (Pub. L. 111-117) under the Title I demonstration authority (Part E, Section 1502 of the ESEA).

Dated: August 1, 2014.

Deborah Delisle,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2014-18607 Filed 8-5-14; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY**Office of Energy Efficiency and Renewable Energy****Request for Information (RFI) on Advanced Manufacturing Office Software Tools**

AGENCY: Office of Energy Efficiency and Renewable Energy (EERE), Department of Energy.

ACTION: Notice of posting for public comment, a Request for Information (RFI) on Advanced Manufacturing Office Software Tools.

SUMMARY: The U.S. Department of Energy (DOE) invites public comment on its Request for Information (RFI) number DE-FOA-0001165 regarding Advanced Manufacturing Office Software Tools. The RFI document is posted at <https://eere-exchange.energy.gov/>.

EERE's Advanced Manufacturing Office (AMO) seeks information from industry, academia, research laboratories, government agencies, and other stakeholders on issues related to market opportunities to enhance and expand upon certain AMO system software tools and related assets. At the present time these software tool resources/assets are primarily maintained and managed by the U.S. Department of Energy's Advanced Manufacturing Office. This RFI seeks information to assist with the transition of these resources to be primarily or solely managed by a third party (or parties). AMO is particularly interested in business strategies to ensure:

- The resource content is maintained, improved and enhanced.
- The resources remain available to the industrial sector.
- The current and future market needs for these system assets are addressed.
- Adaptation to rapidly changing and progressing electronic and IT infrastructure is embraced and addressed.

This is solely a request for information and not a Funding Opportunity Announcement (FOA). EERE is not accepting applications.

DATES: Responses to the RFI must be received on or before September 30, 2014.

ADDRESSES: The complete RFI document is located at <https://eere-exchange.energy.gov/>.

FOR FURTHER INFORMATION CONTACT: Responses to the RFI and questions should be sent via email or email attachment to AMOTools@ee.doe.gov. Further instruction can be found in the

RFI document posted on EERE Exchange.

SUPPLEMENTARY INFORMATION: The RFI is not a Funding Opportunity Announcement (FOA); therefore, EERE is not accepting applications at this time. EERE may issue a FOA in the future based on or related to the content and responses to the RFI; however, EERE may also elect not to issue a FOA. There is no guarantee that a FOA will be issued as a result of the RFI. Responding to the RFI does not provide any advantage or disadvantage to potential applicants if EERE chooses to issue a FOA regarding the subject matter. Final details, including the anticipated award size, quantity, and timing of EERE funded awards, will be subject to Congressional appropriations and direction.

Any information obtained as a result of the RFI is intended to be used by the Government on a non-attribution basis for planning and strategy development; the RFI does not constitute a formal solicitation for proposals or abstracts. Responses to the RFI will be treated as information only. EERE will review and consider all responses in its formulation of program strategies for the identified materials of interest that are the subject of this request. EERE will not provide reimbursement for costs incurred in responding to the RFI. Respondents are advised that EERE is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted under the RFI. Responses to the RFI do not bind EERE to any further actions related to this topic.

Issued in Washington, DC, on July 25, 2014.

Mark A. Johnson,

Director, Advanced Manufacturing Office, Energy Efficiency and Renewable Energy.

[FR Doc. 2014-18570 Filed 8-5-14; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****Combined Notice of Filings #1**

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC14-119-000.

Applicants: Grays Harbor Energy LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act and Request for Waivers and Expedited Action of Grays Harbor Energy LLC.

Filed Date: 7/29/14.

Accession Number: 20140729-5140.

Comments Due: 5 p.m. ET 8/19/14.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10-2984-011.

Applicants: Merrill Lynch

Commodities, Inc.

Description: Second Supplement to June 21, 2013 Updated Market Power Analysis for the Southwest Region of Merrill Lynch Commodities, Inc.

Filed Date: 7/29/14.

Accession Number: 20140729-5146.

Comments Due: 5 p.m. ET 8/19/14.

Docket Numbers: ER11-3643-000.

Applicants: PacifiCorp.

Description: Refund Report Filing (2013 True-Up and Schedule 5 & 6) to be effective N/A.

Filed Date: 7/30/14.

Accession Number: 20140730-5067.

Comments Due: 5 p.m. ET 8/20/14.

Docket Numbers: ER13-1489-003.

Applicants: Quantum Lake Power, LP.

Description: Amendment containing Workpapers of Dr. John R. Morris to March 26, 2014 Notification of Non-Material Change in Status of Quantum Lake Power, LP.

Filed Date: 7/29/14.

Accession Number: 20140729-5145.

Comments Due: 5 p.m. ET 8/19/14.

Docket Numbers: ER13-1489-003.

Applicants: Quantum Lake Power, LP.

Description: Amendment to March 26, 2014 Notification of Non-Material Change in Status of Quantum Lake Power, LP.

Filed Date: 7/29/14.

Accession Number: 20140729-5151.

Comments Due: 5 p.m. ET 8/19/14.

Docket Numbers: ER14-1872-000.

Applicants: Midcontinent

Independent System Operator, Inc.

Description: 2014-07-30 SA 2650 METC E&P Supplement Filing to be effective N/A.

Filed Date: 7/30/14.

Accession Number: 20140730-5039.

Comments Due: 5 p.m. ET 8/20/14.

Docket Numbers: ER14-2223-000.

Applicants: Sabine Cogen, LP.

Description: Second Amendment to June 19, 2014 Sabine Cogen, LP tariff filing.

Filed Date: 7/29/14.

Accession Number: 20140729-5147.

Comments Due: 5 p.m. ET 8/19/14.

Docket Numbers: ER14-2526-000.

Applicants: Southern California Edison Company.

Description: Service Agreement for Wholesale Distribution Service with City of Industry to be effective 7/31/2014.

Filed Date: 7/30/14.
Accession Number: 20140730–5002.
Comments Due: 5 p.m. ET 8/20/14.
Docket Numbers: ER14–2527–000.
Applicants: PJM Interconnection, L.L.C.
Description: Service Agreement No. 3686; Queue No. Y3–023 to be effective 7/1/2014.

Filed Date: 7/30/14.
Accession Number: 20140730–5043.
Comments Due: 5 p.m. ET 8/20/14.
Docket Numbers: ER14–2528–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: 2014–07–30 Attachment P GFA Clean-up to be effective 9/29/2014.

Filed Date: 7/30/14.
Accession Number: 20140730–5045.
Comments Due: 5 p.m. ET 8/20/14.
Docket Numbers: ER14–2529–000.
Applicants: Pacific Gas and Electric Company.
Description: Transmission Owner Rate Case 2015 (TO16) to be effective 10/1/2014.

Filed Date: 7/30/14.
Accession Number: 20140730–5071.
Comments Due: 5 p.m. ET 8/20/14.
Docket Numbers: ER14–2530–000.
Applicants: Arizona Public Service Company.
Description: Service Agreement No. 218, Exhibit F Revision No. 8—Mead Phoenix Project to be effective 7/1/2014.

Filed Date: 7/30/14.
Accession Number: 20140730–5081.
Comments Due: 5 p.m. ET 8/20/14.
Docket Numbers: ER14–2531–000.
Applicants: PJM Interconnection, L.L.C.
Description: Service Agreement No. 3911; Queue No. Y3–024 to be effective 7/1/2014.

Filed Date: 7/30/14.
Accession Number: 20140730–5082.
Comments Due: 5 p.m. ET 8/20/14.
Docket Numbers: ER14–2532–000.
Applicants: Tampa Electric Company.
Description: TEC's Compliance Filing Order 792 to be effective 8/1/2014.

Filed Date: 7/30/14.
Accession Number: 20140730–5087.
Comments Due: 5 p.m. ET 8/20/14.
Docket Numbers: ER14–2533–000.
Applicants: MATL LLP.
Description: Replacement for 792 Language to be effective 8/1/2014.

Filed Date: 7/30/14.
Accession Number: 20140730–5093.
Comments Due: 5 p.m. ET 8/20/14.
Docket Numbers: ER14–2534–000.
Applicants: New England Power Company.
Description: New England Power Filing of SGIA with Centennial Island

Hydroelectric Company to be effective 6/23/2014.

Filed Date: 7/30/14.
Accession Number: 20140730–5097.
Comments Due: 5 p.m. ET 8/20/14.
Docket Numbers: ER14–2535–000.
Applicants: PJM Interconnection, L.L.C.
Description: Service Agreement No. 3330; Queue No. X1–095 to be effective 7/2/2014.

Filed Date: 7/30/14.
Accession Number: 20140730–5104.
Comments Due: 5 p.m. ET 8/20/14.
Docket Numbers: ER14–2536–000.
Applicants: California Independent System Operator Corporation.
Description: 2014–07–30 Contingency Reserve Cost Allocation to be effective 10/1/2014.

Filed Date: 7/30/14.
Accession Number: 20140730–5113.
Comments Due: 5 p.m. ET 8/20/14.
Docket Numbers: ER14–2537–000.
Applicants: Florida Power & Light Company.
Description: FPL and Landfill Energy Systems, LLC Service Agreement No. 327 to be effective 11/1/2014.

Filed Date: 7/30/14.
Accession Number: 20140730–5124.
Comments Due: 5 p.m. ET 8/20/14.
 Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES14–46–000.
Applicants: Ameren Illinois Company.
Description: Application for Financing Authorization under Federal Power Act Section 204 of Ameren Illinois Company.

Filed Date: 7/30/14.
Accession Number: 20140730–5092.
Comments Due: 5 p.m. ET 8/20/14.
 Take notice that the Commission received the following land acquisition reports:

Docket Numbers: LA14–2–000.
Applicants: Auburndale Peaker Energy Center, LLC, Bethpage Energy Center 3, LLC, Calpine Bethlehem, LLC, Calpine Construction Finance Co., L.P., Calpine Energy Services, L.P., Calpine Gilroy Cogen, L.P., Calpine Greenleaf, Inc., Calpine Mid-Atlantic Generation, LLC, Calpine Mid-Atlantic Marketing, LLC, Calpine Mid Merit, LLC, Calpine New Jersey Generation, LLC, Calpine Newark, LLC, Calpine Power America—CA, LLC, Calpine Vineland Solar, LLC, CCFC Sutter Energy, LLC, CES Marketing V, LLC, CES Marketing IX, LLC, CES Marketing X, LLC, CPN Bethpage 3rd Turbine, Inc., Creed Energy Center, LLC, Delta Energy Center, LLC, Geysers Power Company,

LLC, Gilroy Energy Center, LLC, Goose Haven Energy Center, LLC, Hermiston Power, LLC, KIAC Partners, Los Esteros Critical Energy Facility, LLC, Los Medanos Energy Center, LLC, Mankato Energy Center, LLC, Metcalf Energy Center, LLC, Morgan Energy Center, LLC, Nissequogue Cogen Partners, O.L.S. Energy-Agnews, Inc., Osprey Energy Center, LLC, Otay Mesa Energy Center, LLC, Pastoria Energy Facility L.L.C., Pine Bluff Energy, LLC, Power Contract Financing, L.L.C., RockGen Energy, LLC, Russell City Energy Company, LLC, South Point Energy Center, LLC, TBG Cogen Partners, Westbrook Energy Center, LLC, Zion Energy LLC.

Description: Quarterly Land Acquisition Report of the Calpine MBR Sellers.

Filed Date: 7/29/14.
Accession Number: 20140729–5136.
Comments Due: 5 p.m. ET 8/19/14.
Docket Numbers: LA14–2–000.
Applicants: Cedar Creek II, LLC, Copper Mountain Solar 1, LLC, Copper Mountain Solar 2, LLC, Copper Mountain Solar 3, LLC, Energia Sierra Juarez U.S., LLC, Flat Ridge 2 Wind Energy LLC, Fowler Ridge II Wind Farm LLC, Mehoopany Wind Energy LLC, Mesquite Power, LLC, Mesquite Solar 1, LLC, San Diego Gas & Electric Company, Semptra Generation, LLC, Termoelectrica U.S., LLC.

Description: Quarterly Land Acquisition Report of Semptra Generation, LLC, et. al.

Filed Date: 7/29/14.
Accession Number: 20140729–5137
Comments Due: 5 p.m. ET 8/19/14.
Docket Numbers: LA14–2–000.
Applicants: All Dams Generation, LLC, Arlington Valley Solar Energy II, LLC, Bluegrass Generation Company, L.L.C., Calhoun Power Company, LLC, Carville Energy LLC, Centinela Solar Energy, LLC, Cherokee County Cogeneration Partners, LLC, Columbia Energy LLC, Decatur Energy Center, LLC, DeSoto County Generating Company, LLC, Doswell Limited Partnership, Lake Lynn Generation, LLC, Las Vegas Power Company, LLC, LS Power Marketing, LLC, LSP University Park, LLC, Mobile Energy LLC, Oneta Power, LLC, PE Hydro Generation, LLC, Renaissance Power, L.L.C., Riverside Generating Company, L.L.C., Rocky Road Power, LLC, Santa Rosa Energy Center, LLC, Seneca Generation, LLC, Tilton Energy LLC, University Park Energy, LLC, Wallingford Energy LLC, West Deptford Energy, LLC.

Description: Quarterly Land Acquisition Report of the LS MBR Sellers.

Filed Date: 7/29/14.

Accession Number: 20140729–5138

Comments Due: 5 p.m. ET 8/19/14.

Docket Numbers: LA14–2–000.

Applicants: Iberdrola Renewables, LLC, Atlantic Renewable Projects II LLC, Barton Windpower LLC, Big Horn Wind Project LLC, Big Horn II Wind Project LLC, Blue Creek Wind Farm LLC, Buffalo Ridge I LLC, Buffalo Ridge II LLC, Casselman Windpower LLC, Colorado Green Holdings LLC, Dillon Wind LLC, Dry Lake Wind Power, LLC, Dry Lake Wind Power II LLC, Elk River Windfarm, LLC, Elm Creek Wind, LLC, Elm Creek Wind II LLC, Farmers City Wind, LLC, Flat Rock Windpower LLC, Flat Rock Windpower II LLC, Flying Cloud Power Partners, LLC, Groton Wind, LLC, Hardscrabble Wind Power LLC, Hay Canyon Wind LLC, Juniper Canyon Wind Power LLC, Klamath Energy LLC, Klamath Generation LLC, Klondike Wind Power LLC, Klondike Wind Power II LLC, Klondike Wind Power III LLC, Leaning Juniper Wind Power II LLC, Lempster Wind, LLC, Locust Ridge Wind Farm, LLC, Locust Ridge II, LLC, Manzana Wind LLC, MinnDakota Wind LLC, Moraine Wind LLC, Moraine Wind II LLC, Mountain View Power Partners III, LLC, New England Wind, LLC, New Harvest Wind Project LLC, Northern Iowa Windpower II LLC, Pebble Springs Wind LLC, Providence Heights Wind, LLC, Rugby Wind LLC, San Luis Solar LLC, Shiloh I Wind Project, LLC, South Chestnut LLC, Star Point Wind Project LLC, Streater-Cayuga Ridge Wind Power LLC, Trimont Wind I LLC, and Twin Buttes Wind LLC.

Description: Quarterly Land Acquisition Report of the Iberdrola MBR Sellers.

Filed Date: 7/29/14.

Accession Number: 20140729–5139.

Comments Due: 5 p.m. ET 8/19/14.

Docket Numbers: LA14–2–000.

Applicants: Blue Sky East, LLC, Canandaigua Power Partners, LLC, Canandaigua Power Partners II, LLC, Erie Wind, LLC, Evergreen Wind Power, LLC, Evergreen Wind Power III, LLC, First Wind Energy Marketing, LLC, Longfellow Wind, LLC, Milford Wind Corridor Phase I, LLC, Milford Wind Corridor Phase II, LLC, Palouse Wind, LLC, Niagara Wind Power, LLC, Stetson Holdings, LLC, Stetson Wind II, LLC, Vermont Wind, LLC.

Description: Quarterly Land Acquisition Report of the First Wind MBR Companies.

Filed Date: 7/30/14.

Accession Number: 20140730–5028.

Comments Due: 5 p.m. ET 8/20/14.

Docket Numbers: LA14–2–000.

Applicants: Southern Company Services, Inc., Alabama Power Company, Georgia Power Company, Gulf Power Company, Mississippi Power Company, Southern Power Company.

Description: Quarterly Land Acquisition Report of Southern Company Services, Inc. (as Agent).

Filed Date: 7/30/14.

Accession Number: 20140730–5056.

Comments Due: 5 p.m. ET 8/20/14.

Docket Numbers: LA14–2–000.

Applicants: Alta Wind I, LLC, Alta Wind II, LLC, Alta Wind III, LLC, Alta Wind IV, LLC, Alta Wind V, LLC, Alta Wind X, LLC, Alta Wind XI, LLC, ArcLight Energy Marketing, LLC, Badger Creek Limited, Coso Geothermal Power Holdings, LLC, Double “C” Limited, High Sierra Limited, Kern Front Limited, Oak Creek Wind Power, LLC, TGP Energy Management, LLC, and Victory Garden Phase IV, LLC.

Description: Quarterly Land Acquisition Report of Alta Wind I, LLC, et. al.

Filed Date: 7/30/14.

Accession Number: 20140730–5106.

Comments Due: 5 p.m. ET 8/20/14.

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: July 30, 2014.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2014–18580 Filed 8–5–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for electronic review at the Commission in the Public Reference Room or may be viewed on the Commission’s Web site at <http://www.ferc.gov> using the eLibrary link.

Enter the docket number, excluding the last three digits, in the docket number field to access the document. For

assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov

ferc.gov or toll free at (866) 208-3676, or for TTY, contact (202) 502-8659.

PROHIBITED

Docket No.	File date	Presenter or requester
1. CP14-96-000	7-3-14	Building and Construction Trades Council of Westchester and Putnam Counties, New York, AFL-CIO.
2. ER14-897-001	7-15-14	Estancia Valley Economic Development Association.
3. CP13-113-000	7-22-14	MoveOn.org. ¹
4. EL11-66-000	7-24-14	Clearview Energy Partners LLC.

EXEMPT

Docket No.	File date	Presenter or requester
1. EL14-40-000	7-10-14	Hon. Raul Ruiz, M.D.
2. P-13948-002; P-13994-002	7-10-14	Commission Staff. ²
3. CP14-125-000	7-14-14	Hon. Mary L. Landrieu.
4. ER14-2056-000	7-14-14	Hon. Pat Toomey.
5. ER14-2056-000	7-15-14	Hon. Chris Collins.
6. ER14-897-000	7-15-14	State of New Mexico, Commissioner of Public Lands, Ray Powell.
7. P-13590-000	7-15-14	Commission Staff. ³
8. ER14-897-000	7-15-14	Torrance County, New Mexico Commissioners. ⁴
9. CP12-507-000; CP12-508-000	7-14-14	Commission Staff. ⁵
10. CP13-483-000; CP13-492-000	7-17-14	Commission Staff. ⁶
11. P-14345-001	7-22-14	Commission Staff. ⁷
12. CP13-499-000; CP13-502-000	7-22-14	Hon. Kirsten Gillibrand.
13. CP13-193-000	7-22-14	Members of Congress. ⁸
14. CP13-193-000	7-23-14	Hon. Marco Rubio.
15. CP13-551-000	7-23-14	Members of Congress. ⁹
16. CP13-483-000	7-28-14	Commission Staff. ¹⁰

Dated: July 29, 2014.

Kimberly D. Bose,
Secretary.

[FR Doc. 2014-18532 Filed 8-5-14; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2010-0173; FRL-9914-12]

Approach for Estimating Exposures and Incremental Health Effects From Lead Due to Renovation, Repair, and Painting Activities in Public and Commercial Buildings; Notice of Availability and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is currently in the process of determining whether or not lead-based paint hazards are created by renovation, repair, and painting (RRP) activities in public and commercial buildings (P&CBs), as required under the Toxic Substances Control Act (TSCA). EPA is making the following documents available for public review and comment before they undergo external peer review: "Approach for Estimating Exposures and Incremental Health Effects from Lead Due to Renovation, Repair, and Painting Activities in Public and Commercial Buildings" (the Approach); the detailed appendices for the Approach; and a supplementary report, entitled "Developing a Concentration-Response Function for Pb Exposure and Cardiovascular Disease-Related Mortality." Together, these documents describe a methodology for estimating exposures and incremental health

effects created by renovations of P&CBs. This methodology could be used to identify and evaluate hazards from RRP in P&CBs. Also available for public review and comment is a list of charge questions that will be directed to the external peer reviewers for the Approach.

DATES: Comments must be submitted September 22, 2014.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2010-0173, by one of the following methods:

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

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

⁸ Hons. Nydia M. Velazquez and Luis V. Gutierrez.

⁹ Hons. Rush Holt, Robert Menendez, Cory Booker, and Frank Pallone, Jr.

¹⁰ Record of July 24, 2014 Conference Call with Jordon Cove.

¹ Thirty-two (32) emailed comments.

² Summary of July 10, 2014 telephone call with Snohomish County Public Utility District No. 1.

³ Summary of June 26, 2014 telephone conversation with Lockhart Power Company regarding May 15, 2014 filing.

⁴ Lonnie Freyburger, LeRoy Candelaria, and Leanne Tapia.

⁵ Meeting summary of July 14, 2014 LNG Engineering Conference Call.

⁶ Notes from July 16, 2014 bi-weekly telephone conference call with federal cooperating agencies regarding production of environmental impact statement.

⁷ Record of July 22, 2014 email communication license applicant for Rock River Beach Project.

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

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

FOR FURTHER INFORMATION CONTACT: For technical information contact: Stan Barone, Jr., Risk Assessment Division (7403M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number (202) 564-1169; email address: barone.stan@epa.gov.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including independent contractors and contracting companies involved in renovation, repair, and painting, as well as academics and members of the public interested in environmental and human health assessment and the assessment of chemical risks. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

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

1. **Submitting confidential business information (CBI).** Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. **Tips for preparing your comments.** When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

EPA is currently in the process of determining whether or not lead-based paint hazards are created by RRP activities in P&CBs, as required under TSCA, Subtitle IV (15 U.S.C. 2681 *et seq.*). For those renovation activities in P&CBs that create lead-based paint hazards, TSCA directs EPA to address the hazards through regulation.

EPA recently published in the **Federal Register** of May 30, 2014 (Ref. 1) a document for public comment, entitled “Framework for Identifying and Evaluating Lead-Based Paint Hazards from Renovation, Repair, and Painting Activities in Public and Commercial Buildings” (Ref. 2). This Framework document described, in general terms, how EPA could identify and evaluate hazards in P&CBs.

The current document, entitled “Approach for Estimating Exposures and Incremental Health Effects from Lead Due to Renovation, Repair, and Painting Activities in Public and Commercial Buildings” (Ref. 3) describes how EPA is modeling the potential overall magnitude and distribution of renovation-related health effects due to lead exposure from a renovation in a P&CB, taking into account background lead levels when no such renovation exposure occurs. Based on information developed through the Approach, renovation-related health effects will be estimated

as the difference between total health effects (background plus renovation-related) and background. Exposures from renovation activities that disturb lead-based paint are connected to subsequent health effects in children and adults through modeling. Separate Monte-Carlo based models were constructed for the analysis of exterior renovations of P&CBs and interior renovations of P&CBs.

The Monte Carlo analysis is designed to capture potential population-level variability within each exposure scenario and, as such, approximates the potential distribution of effects to the part of the U.S. population who would fall within any scenario. However, the results presented in the Approach are not representative of an overall distribution of the entire U.S. population. All scenarios are not equally likely, and in fact some scenarios may be very unlikely to occur. In the future, EPA plans to estimate how many people may be reasonably expected to be exposed in different scenarios.

After further analysis, the full results of the Approach, along with information about how often any scenario is expected to actually occur, will be used to consider whether or not renovation activities in P&CBs create hazards and, if so, what mitigation measures may be appropriate. EPA plans to consider renovation-related dust loadings, blood lead, and health effect changes across exposure scenarios in order to evaluate whether a hazard occurs. A detailed discussion of the additional analyses and considerations that would inform EPA's process of making a hazard finding, or a finding of no hazard, are contained in the Approach. By itself, the Approach methodology cannot be used to determine whether hazards exist from P&CB renovations. EPA will need to conduct additional analyses and make certain science policy decisions in order to determine whether such hazards exist.

EPA's Office of Pollution Prevention and Toxics (OPPT) has identified the Approach as an influential product and according to EPA peer review guidance is conducting an external peer review of that document, supplemental files, appendices (Ref. 4), and attendant models used for exposure scenarios. The external peer reviewers will assess the accuracy and content of the Approach, ensuring that the Approach and initial results are scientifically sound. The external peer review will also address the supplemental documents, which include detailed appendices for the Approach and a supplementary report relating lead exposure to Cardiovascular

Disease (CVD) mortality and proposing an approach to quantify adult health benefits from a reduction in lead (Pb) exposure for CVD mortality, entitled "Developing a Concentration-Response Function for Pb Exposure and Cardiovascular Disease-Related Mortality" (Ref. 5). The panel peer review meetings are expected to occur later in 2014, and the public will have an opportunity to review and comment on the materials given to the external peer reviewers.

III. Request for Comment

EPA is requesting public review and comment on all aspects of the Approach and its supplemental files, appendices, attendant models, peer review charge (Ref. 6), and particularly related to the following:

- The utility of the Approach for estimating exposures through summarizing building use configuration types and human-activity patterns to incorporate variability across the wide variety of P&CBs.
- The utility of the updated Leggett Model (original model described in Leggett 1993 (Ref. 7); updated model described in the appendices to the Approach (Ref. 4)) to estimate blood lead levels for both children and adults, and specifically the use of the various outputs derived from the Leggett Model (concurrent blood lead, lifetime blood lead, and bone lead) in concentration-response curves for children and adults.
- The utility of concentration-response functions for health endpoints in both children and adults for assessing risk to human health inside P&CBs as a result of P&CB renovations.

IV. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Lead; Framework for Identifying and Evaluating Lead-Based Paint Hazards From Renovation, Repair, and Painting Activities in Public and Commercial Buildings. **Federal Register** (79 FR 31072, May 30, 2014) (FRL-9910-44).

2. EPA. Framework for Identifying and Evaluating Lead-Based Paint Hazards From Renovation, Repair, and Painting Activities in Public and Commercial Buildings. May 2014. Document ID number EPA-HQ-OPPT-2010-0173-0196. Also available at http://www2.epa.gov/sites/production/files/2014-05/documents/lead_pncb_framework_document.pdf.

3. EPA. Approach for Estimating Exposures and Incremental Health Effects from Lead Due to Renovation, Repair, and Painting Activities in Public and Commercial Buildings. July 2014. Docket ID number EPA-HQ-OPPT-2010-0173.

4. EPA. Appendices to the Approach for Estimating Exposures and Incremental Health Effects from Lead due to Renovation, Repair, and Painting Activities in Public and Commercial Buildings. July 2014. Docket ID number EPA-HQ-OPPT-2010-0173.

5. EPA. Developing a Concentration-Response Function for Pb Exposure and Cardiovascular Disease-Related Mortality. July 2014. Docket ID number EPA-HQ-OPPT-2010-0173.

6. EPA. Charge Questions for Approach for Estimating Exposures and Incremental Health Effects from Lead due to Renovation, Repair, and Painting Activities in Public and Commercial Buildings. July 2014. Docket ID number EPA-HQ-OPPT-2010-0173.

7. Leggett, R.W. An age-specific kinetic model of lead metabolism in humans. *Environmental Health Perspectives*. 101:598-616. 1993.

List of Subjects

Environmental protection, Business and industry, Commercial buildings, Lead, Peer review, Renovation, Risk assessment.

Dated: July 28, 2014.

Wendy C. Hamnett,

Director, Office of Pollution Prevention and Toxics.

[FR Doc. 2014-18357 Filed 8-5-14; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2009-1017; FRL-9914-09]

Product Cancellation Order for Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the cancellations, voluntarily requested by the registrants and accepted by the Agency, of the products listed in Table 1 of Unit II., pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This cancellation order follows a May 20, 2014 **Federal Register** Notice of Receipt of Requests from the registrants listed in Table 2 of Unit II. to voluntarily cancel these product registrations. In the May 20, 2014 **Federal Register** notice, EPA indicated that it would issue an order implementing the cancellations, unless the Agency received substantive

comments within the 30-day comment period that would merit its further review of these requests, or unless the registrants withdrew their requests. The Agency received comments on the May 20, 2014 **Federal Register** notice but none merited its further review of the requests. Further, the registrants did not withdraw their requests. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested cancellations. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this cancellation order, including any existing stocks provisions.

DATES: The cancellations are effective August 6, 2014.

FOR FURTHER INFORMATION CONTACT: John W. Pates, Jr., Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 308-8195; email address: pates.john@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

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-2009-1017, 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. What action is the Agency taking?

This notice announces the cancellation, as requested by registrants,

of products registered under FIFRA section 3 (7 U.S.C. 136a). These registrations are listed in sequence by

registration number in Table 1 of this unit.

TABLE 1—PRODUCT CANCELLATIONS

EPA Registration No.	Product name	Chemical name
000264–00805	Thiacloprid Technical Insecticide	Thiacloprid
000264–00806	Calypso 4 Flowable Insecticide	Thiacloprid
000352–00593	Accent Gold Herbicide	Clopyralid, nicosulfuron, rimsulfuron, and flumetsulam
000352–00612	DuPont Accent Gold WDG Herbicide	Clopyralid, nicosulfuron, rimsulfuron, and flumetsulam
000352–00792	DuPont DPX–KJM44 80XP Turf Herbicide	Aminocyclopyrachlor methyl ester
000352–00794	DuPont DPX–MAT28 50SG Turf Herbicide	Aminocyclopyrachlor
000352–00797	DuPont DPX–KJM44 0.064G Turf Herbicide + Fertilizer	Aminocyclopyrachlor methyl ester
000352–00800	DuPont DPX–KJM44 0.073G Lawn Herbicide + Fertilizer	Aminocyclopyrachlor methyl ester
000352–00803	DuPont DPX–KJM44 0.053G Lawn Herbicide + Fertilizer	Aminocyclopyrachlor methyl ester
000352–00804	DuPont DPX–KJM44 0.049G Lawn Herbicide + Fertilizer	Aminocyclopyrachlor methyl ester
000352–00807	DuPont DPX–KJM44 0.033G Lawn Herbicide + Fertilizer	Aminocyclopyrachlor methyl ester
000352–00811	DuPont DPX–KJM44 0.02G Lawn Herbicide + Fertilizer	Aminocyclopyrachlor methyl ester
000352–00813	DuPont DPX–MAT28 0.05G Turf Herbicide + Fertilizer	Aminocyclopyrachlor
000352–00814	DuPont DPX–MAT28 0.03G Turf Herbicide + Fertilizer	Aminocyclopyrachlor
000352–00815	DuPont DPX–MAT28 0.068G Lawn Herbicide + Fertilizer	Aminocyclopyrachlor
000432–01362	Premise 0.5 SC	Imidacloprid
000464–00662	S.S.T. Sump Saver Tablets	2-(hydroxymethyl)-2-nitro-1,3-propanediol
001270–00255	Zep Flush 'N Kill DM	S-bioallethrin and deltamethrin
001448–00379	Busan 2020F	Poly(oxy-1,2-ethanediyl(dimethylimino)-1,2-ethanediyl(dimethylimino)-1,2-ethanediyl dichloride)
001448–00380	Busan 2020	Poly(oxy-1,2-ethanediyl(dimethylimino)-1,2-ethanediyl(dimethylimino)-1,2-ethanediyl dichloride)
001448–00396	WSKT	Poly(oxy-1,2-ethanediyl(dimethylimino)-1,2-ethanediyl(dimethylimino)-1,2-ethanediyl dichloride); 5-chloro-2-methyl-3(2H)-isothiazolone; and 2-methyl-3(2H)-isothiazolone
001448–00397	Busan 1174	Poly(oxy-1,2-ethanediyl(dimethylimino)-1,2-ethanediyl(dimethylimino)-1,2-ethanediyl dichloride); 5-chloro-2-methyl-3(2H)-isothiazolone; and 2-methyl-3(2H)-isothiazolone
001448–00400	PCA 10	Poly(oxy-1,2-ethanediyl(dimethylimino)-1,2-ethanediyl(dimethylimino)-1,2-ethanediyl dichloride)
008033–00012	Equinox Herbicide	Tepraloxymid
008033–00013	BAS 620 H MUP	Tepraloxymid
010163–00279	Milbemectin Technical Miticide/Insecticide	Milbemectin (A mixture of ≥70% milbemycin A4, and ≤30% milbemycin A3)
010163–00280	Ultiflora Miticide/Insecticide	Milbemectin (A mixture of ≥70% milbemycin A4, and ≤30% milbemycin A3)
028293–00167	Unicorn Residual House and Carpet Spray	Bioallethrin, MGK 264 and permethrin
028293–00192	Unicorn House and Carpet Spray #5	Bioallethrin, MGK 264, piperonyl butoxide, and esfenvalerate
028293–00196	Unicorn House and Carpet Spray #6	Bioallethrin, MGK 264, piperonyl butoxide, and esfenvalerate
028293–00332	Unicorn Flying & Crawling Insect Killer IV	S-bioallethrin and deltamethrin
028293–00334	Unicorn Flying & Crawling Insect Killer V	S-bioallethrin and deltamethrin
028293–00336	Unicorn Flying & Crawling Insect Killer III	S-bioallethrin and deltamethrin
054382–00003	Tactic Emulsifiable Concentrate Miticide/Insecticide	Amitraz
066330–00295	Iprodione Technical 97.5%	Iprodione
066330–00329	Iprodione Technical 98%	Iprodione
067071–00053	Acticide MKW 1	Octhilinone; carbamic acid; butyl-, 3-iodo-2- propynyl ester; and diuron
070627–00071	Raid Institutional Flying Insect Killer	<i>c</i> -allethrin, phenothrin, and tetramethrin
071368–00062	Assert Herbicide	Imazamethabenz
071368–00063	Assert Herbicide Technical	Imazamethabenz
075630–00001	Zinc Borate	Zinc borate (3ZnO, 2B ₂ O ₃ , 3.5H ₂ O; mw 434.66)
083558–00020	Mepiquat Chloride Technical	Mepiquat chloride
085678–00027	Iprodione Technical	Iprodione
087290–00014	Willowood Imidacloprid 4SC	Imidacloprid
087290–00021	Willowood Imidacloprid 2SC	Imidacloprid
ME030004	Accord Concentrate	Glyphosate-isopropylammonium
ME980001	Confirm 2F Insecticide	Tebufenozide

The allethrin series of pyrethroid insecticides includes the Product Chemical (PC) codes for: Bioallethrin (004003), esbiol (004004), esbiothrin (004007, formerly 004003/004004), and pynamin forte (004005). The technical registrants for the allethrins, Sumitomo Chemical Company Limited (Sumitomo)

and Valent BioSciences Corporation (Valent), cancelled all of the allethrins technical products effective September 30, 2015, and cancelled their allethrins end-use product registrations effective December 31, 2016. Because the allethrins technical products have been cancelled, several other registrants for

allethrins end-use products listed in this notice have requested cancellation with dates consistent with those specified for the Valent and Sumitomo allethrins end-use products. The cancellation of the end-use products listed in Table 2 of this unit are effective December 31, 2016.

TABLE 2—PRODUCT CANCELLATIONS FOR ALLETHRIN END-USE PRODUCTS EFFECTIVE DECEMBER 31, 2016

EPA Registration No.	Product name	Chemical name
000004–00461	Bonide Crawling Insect Killer	Deltamethrin and S-bioallethrin
000498–00167	SprayPak Ant & Roach Killer Formula 2 With Esfenvalerate.	Bioallethrin, MGK 264, piperonyl butoxide, and esfenvalerate
000498–00192	Champion Sprayon Flying & Crawling Insect Killer Formula II.	S-Bioallethrin and deltamethrin
000499–00362	Whitmire PT 515 Wasp-Freeze Wasp and Hornet Killer.	Bioallethrin and phenothrin
003095–00026	PIC Mosquito Repellent Coils	<i>d</i> -Allethrin
004822–00283	Raid House and Garden Bug Killer Formula 7	<i>d</i> -Allethrin and phenothrin
004822–00284	Raid Formula 5 Flying Insect Killer	<i>d</i> -Allethrin, piperonyl butoxide, and phenothrin
004822–00469	Repellent LMO	<i>d</i> -Allethrin
004822–00501	Snake II	Bioallethrin
004822–00578	H7A–US	Tetramethrin, phenothrin, and <i>d</i> -allethrin
004822–00580	H7A–US HG	Tetramethrin, phenothrin, and <i>d</i> -allethrin
006218–00043	Summit Mistocide-B	S-bioallethrin, MGK 264, and piperonyl butoxide
009688–00256	Chemsico Aerosol Insecticide DS	S-bioallethrin and deltamethrin
009688–00306	TAT Roach & Ant With Residual Action 2491	Bioallethrin, MGK 264, piperonyl butoxide, and esfenvalerate
010807–00437	Konk Insecticide Foam	Bioallethrin, MGK 264, and permethrin
070385–00004	Microban X–590 Institutional Spray	Bioallethrin, MGK 264, <i>o</i> -phenylphenol (No inert use), piperonyl butoxide, and benzenemethanaminium, <i>N,N</i> -dimethyl- <i>N</i> -(2-(2-(4-(1,1,3,3-tetramethylbutyl)phenoxy)ethoxy)ethyl)-, chloride

Table 3 of this unit includes the names and addresses of record for all registrants of the products in Table 1 and Table 2 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed in Table 1 of this unit.

TABLE 3—REGISTRANTS OF CANCELLED PRODUCTS

EPA Company No.	Company name and address
4	Bonide Products, Inc. Agent: Registrations By Design, Inc., P.O. Box 1019, Salem, VA 24153–3805
264	Bayer CropScience LP, 2 T.W. Alexander Dr., P.O. Box 12014, Research Triangle Park, NC 27709
352	E.I. DuPont De Nemours and Company (S300/419), 1007 Market St., Wilmington, DE 19898–0001
432	Bayer Environmental Science, A Division of Bayer CropScience LP, 2 T.W. Alexander Dr., P.O. Box 12014, Research Triangle Park, NC 27709

TABLE 3—REGISTRANTS OF CANCELLED PRODUCTS—Continued

EPA Company No.	Company name and address
464	The Dow Chemical Co., Agent: The Dow Chemical Company, 100 Larkin Center, 1650 Joseph Dr., Midland, MI 48674
498	Chase Products Co., Putting The Best At Your Fingertips, P.O. Box 70, Maywood, IL 60153
499	Whitmire Micro-Gen Research Laboratories, Inc., Agent: BASF Corporation, 3568 Tree Court Industrial Blvd., St. Louis, MO 63122–6682
1270	Zep, Inc., 1310 Seaboard Industrial Blvd., Atlanta, GA 30318
1448	Buckman Laboratories, Inc., 1256 North McLean Blvd., Memphis, TN 38108
3095	PIC Corporation, Agent: Product & Regulatory Associates, LLC, P.O. Box 1683, Voorhees, NJ 08043–9998

TABLE 3—REGISTRANTS OF CANCELLED PRODUCTS—Continued

EPA Company No.	Company name and address
4822	S.C. Johnson & Son, Inc., 1525 Howe St., Racine, WI 53403
6218	Summit Chemical Co., Summit Responsible Solutions, 235 S. Kresson St., Baltimore, MD 21224
8033	Nippon Soda Co., LTD, Agent: Nisso America, Inc., 88 Pine St., 14th Floor, New York, NY 10005
9688	Chemsico, A Division of United Industries Corp., P.O. Box 142642, St. Louis, MO 63114–0642
10163	Gowan Co., P.O. Box 5569, Yuma, AZ 85366–5569
10807	Amrep, Inc., 990 Industrial Park Dr., Marietta, GA 30062
28293	Phaeton Corp., D/B/A Unicorn Laboratories, Agent: Registrations By Design, Inc., P.O. Box 1019, Salem, VA 24153

TABLE 3—REGISTRANTS OF
CANCELLED PRODUCTS—Continued

EPA Company No.	Company name and address
54382	Intervet, Inc., D/B/A Merck Animal Health, 556 Morris Ave., S5-2145A, Summit, NJ 07901
66330	Arysta LifeScience North America, LLC 15401 Weston Parkway, Suite 150 Cary, NC 27513
67071	Thor GmbH, Agent: Thor Specialties, Inc., 50 Waterview Dr., Shelton, CT 06484
70385	ProRestore Products, Agent: Lewis & Harrison, LLC, 122 C St. NW., Suite 505, Washington, DC 20001
70627	Diversey, Inc., 8310-16th St., MS 707, Sturtevant, WI 53177
71368	Nufarm, Inc., Agent: Nufarm Americas, Inc., 4020 Aerial Center Parkway, Suite 1013, Morrisville, NC 27560
75630	Royce Associates, LP, 35 Carlton Ave., East Rutherford, NJ 07073
83558	Celsius Property B.V., Amsterdam (NL), Neuhausen A. RHF Branch, Agent: Makhteshim Agan of North America, Inc., 3120 Highwoods Blvd., Suite 100, Raleigh, NC 27604
85678	RedEagle International, LLC, Agent: Wagner Regulatory Associates, Inc., P.O. Box 640, Hockessin, DE 19707-0640
87290	Willowood, LLC, Agent: Wagner Regulatory Associates, Inc., P.O. Box 640, Hockessin, DE 19707-0640
ME030004, ME980001.	Dow AgroSciences, LLC, 9330 Zionsville Rd., 308/ 2E Indianapolis, IN 46268-1054

III. Summary of Public Comments Received and Agency Response to Comments

During the public comment period, EPA received three comments. One of the comments received was submitted by the registrant Nippon Soda Co., Ltd. c/o Nisso America, Inc. (Nisso) that explained the importance for maintaining the existing tepraloxym dim tolerances for importation purposes through 2018. This request does not pertain to the voluntary cancellation of the registrant's products (008033-00012 and 008033-00013), which have never been marketed in the United States.

The two remaining comments received pertained to pesticide concerns

in general. These two comments did not contain information about any specific product cancellation request. For these reasons, the Agency does not believe that the three comments submitted during the comment period, which referenced importation tolerances and general pesticide concerns, merit further review or a denial of the requests for voluntary cancellation.

IV. Cancellation Order

Pursuant to FIFRA section 6(f) (7 U.S.C. 136d(f)), EPA hereby approves the requested cancellations of the registrations identified in Table 1 of Unit II. Accordingly, the Agency hereby orders that the product registrations identified in Table 1 of Unit II. are canceled. The effective date of the cancellations that are the subject of this notice is August 6, 2014. Any distribution, sale, or use of existing stocks of the products identified in Table 1 of Unit II. in a manner inconsistent with any of the provisions for disposition of existing stocks set forth in Unit VI. are a violation of FIFRA.

V. What is the Agency's authority for taking this action?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the EPA Administrator may approve such a request. The notice of receipt for this action was published for comment in the **Federal Register** of May 20, 2014 (79 FR 28920) (FRL-9909-40). The comment period closed on June 19, 2014.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the cancellation action. The existing stocks provisions for the products subject to this order are as follows.

A. All Products in Table 1 of Unit II. except 000264-00806, 008033-00012, 008033-00013, 054382-00003, 067071-00053, 071368-00062, 087290-00014, 087290-00021)

The registrants may continue to sell and distribute existing stocks of products listed in Table 1 of Unit II. until August 6, 2015, which is 1 year after the publication of this cancellation order in the **Federal Register**. Thereafter, the registrants are prohibited from selling or distributing products listed in Table 1 of Unit II., except for export in accordance with FIFRA section 17 (7 U.S.C. 136o), or proper disposal. Persons other than the registrants may sell, distribute, or use existing stocks of products listed in Table 1 of Unit II. until existing stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products.

B. Product 000264-00806

In a letter to the Agency, the registrant had requested to voluntarily cancel all of its current thiacloprid product and domestic use registrations. In doing so, the registrant requested an 18-month time period to sell and distribute existing stocks of this product. The registrant may continue to sell and distribute existing stocks of product listed in Table 1 of Unit II. until Monday, February 8, 2016, which is 1 year and 6 months after the publication of this cancellation order in the **Federal Register**. Thereafter, the registrant is prohibited from selling or distributing product listed in Table 1 of Unit II., except for export in accordance with FIFRA section 17, or proper disposal. Persons other than the registrant may sell, distribute, or use existing stocks of product listed in Table 1 of Unit II. until existing stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled product.

C. Product 071368-00062

The registrant may continue to sell and distribute existing stocks of product containing imazamethabenz listed in Table 1 of Unit II. until December 31, 2015. Thereafter, registrants, and persons other than the registrants, are prohibited from selling or distributing product containing imazamethabenz listed in Table 1 of Unit II., except for export in accordance with FIFRA section 17, or proper disposal. Existing stocks of product containing imazamethabenz already in the hands of

users can be used legally until such existing stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled product.

D. Products 008033-00012, 008033-00013, 054382-00003, 067071-00053, 087290-00014 and 087290-00021

Registrants have indicated to the Agency via letter and/or written response that due to the last manufacturing date, distribution date, or the absence of marketing in the United States no existing stocks provisions are necessary for them to sell and distribute their product(s).

Registrants are prohibited from selling or distributing products listed in Table 1 of Unit II., except for export in accordance with FIFRA section 17, or proper disposal. Persons other than the registrants may sell, distribute, or use existing stocks of products listed in Table 1 of Unit II. until existing stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products.

E. End-Use Products Listed in Table 2 of Unit II.

The registrants may continue to sell and distribute existing stocks of products listed in Table 2 of Unit II. until December 31, 2016. Thereafter, as of January 1, 2017, registrants are prohibited from selling or distributing products listed in Table 2 of Unit II., except for export in accordance with FIFRA section 17, or proper disposal. Persons other than registrants are allowed to sell, distribute, or use existing stocks of product listed in Table 2 of Unit II. until existing stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled product.

List of Subjects

Environmental protection,
Administrative practice and procedure,
Pesticides and pests.

Dated: July 23, 2014.

Richard P. Keigwin, Jr.,

*Director, Pesticide Re-Evaluation Division,
Office of Pesticide Programs.*

[FR Doc. 2014-18222 Filed 8-5-14; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2013-0049; FRL-9913-53]

Product Cancellation Order for Certain Rodenticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the cancellations, voluntarily requested by the registrant and accepted by the Agency, of certain rodenticide products containing the pesticide active ingredients brodifacoum, difethialone and warfarin, pursuant to section 6(f) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These cancellations are effective January 1, 2015. This cancellation order follows a June 18, 2014, **Federal Register** Notice of Receipt of a Request from the registrant to voluntarily cancel these product registrations. These are not the last products containing these pesticide active ingredients registered for use in the United States. In the June 18, 2014, Notice, EPA indicated that it would issue an order cancelling these products unless the Agency received substantive comments within the 30-day comment period that would merit its further review of these requests. The Agency did not receive any comments on the notice. Further, the registrant has not withdrawn its request. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested cancellations effective January 1, 2015. Any distribution, sale, or use of products cancelled by this order is permitted only in accordance with the provisions of this order concerning existing stocks of the cancelled products.

DATES: The cancellations are effective January 1, 2015.

FOR FURTHER INFORMATION CONTACT: Rusty Wasem, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 305-6979; email address: wasem.russell@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale,

distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

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-2013-0049, 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. What action is the Agency taking?

This notice announces the cancellation, as requested by the registrant, of products registered under FIFRA section 3. These registrations are listed in sequence by registration number in Tables 1, 2, and 3 of this unit.

TABLE 1—WARFARIN PRODUCT CANCELLATIONS

EPA Registration No.	Product name
3282-3	d-CON Concentrate Kills Rats & Mice.
3282-4	d-CON Ready Mixed Kills Rats & Mice.
3282-9	d-CON Mouse Prufe Kills Mice.
3282-15	d-CON Pellets Kills Rats & Mice.

TABLE 2—BRODIFACOUM PRODUCT CANCELLATIONS

EPA Registration No.	Product name
3282-65	d-CON Mouse Prufe II.
3282-66	d-CON Pellets Generation II.
3282-74	d-CON Bait Pellets II.
3282-81	d-CON Ready Mixed Generation II.

TABLE 3—DIFETHIALONE PRODUCT CANCELLATIONS

EPA Registration No.	Product name
3282–85	d-CON Mouse-Prufe III.
3282–86	d-CON Bait Pellets III.
3282–87	d-CON Ready Mix Baitbits III.
3282–88	d-CON Bait Packs III.

Table 4 of this unit includes the name and address of record for the registrant of the products in Tables 1, 2, and 3 of this unit.

TABLE 4—REGISTRANT OF CANCELLED PRODUCTS

EPA Company No.	Company name and address
3282	Reckitt Benckiser, LLC, 399 Interpace Parkway, Parsippany, New Jersey 07054.

III. Summary of Public Comments Received and Agency Response to Comments

During the public comment period provided, EPA received no comments in response to the June 18, 2014, **Federal Register** notice announcing the Agency's receipt of the requests for voluntary cancellations of products listed in Tables 1, 2 and 3.

IV. Cancellation Order

Pursuant to FIFRA section 6(f), EPA hereby approves the requested cancellations of the brodifacoum, difethialone, and warfarin registrations identified in Tables 1, 2, and 3 of Unit II. Accordingly, the Agency orders that the product registrations identified in Tables 1, 2, and 3 of Unit II. are cancelled effective January 1, 2015. Any distribution, sale, or use of existing stocks of the products identified in Tables 1, 2, and 3 of Unit II. in a manner inconsistent with any of the Provisions for Disposition of Existing Stocks set forth in Unit VI. is a violation of FIFRA.

V. What is the Agency's authority for taking this action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be cancelled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the Administrator may approve such a request.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of cancelled pesticide products that are in the United States and that were appropriately packaged, labeled, and released for shipment prior to the effective date of cancellation of the underlying registration. This cancellation order includes the following provisions regarding existing stocks of the registrations identified in Tables 1, 2, and 3:

1. Reckitt Benckiser is permitted to sell and distribute existing stocks to its existing customers until March 31, 2015. During this time period, Reckitt Benckiser is also permitted to ship product for the purpose of returning material back to Reckitt Benckiser or for the purpose of disposal.

2. Reckitt Benckiser is permitted to sell and distribute existing stocks after March 31, 2015, only for the limited purposes of returning material back to Reckitt Benckiser or for disposal.

3. The sale and distribution of existing stocks by persons other than Reckitt Benckiser (e.g., distributors, retailers) is permitted until such stocks are exhausted.

4. Users are permitted to use existing stocks until such stocks are exhausted, provided that such use is consistent with the terms of the previously approved labeling on, or that accompanied, the cancelled product.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: July 24, 2014.

Richard P. Keigwin, Jr.,

*Director, Pesticide Re-evaluation Division,
Office of Pesticide Programs.*

[FR Doc. 2014–18361 Filed 8–5–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2009–1017; FRL–9914–36]

Notice of Receipt of Requests to Voluntarily Cancel Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is issuing a notice of receipt of requests by registrants to voluntarily cancel certain pesticide registrations. EPA intends to grant these requests at the close of the

comment period for this announcement unless the Agency receives substantive comments within the comment period that would merit its further review of the requests, or unless the registrants withdraw their requests. If these requests are granted, any sale, distribution, or use of products listed in this notice will be permitted after the registration has been cancelled only if such sale, distribution, or use is consistent with the terms as described in the final order.

DATES: Comments must be received on or before September 5, 2014.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2009–1017, by one of the following methods:

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

Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

Submit written withdrawal requests by mail to: Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001. ATTN: John W. Pates, Jr.

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

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

FOR FURTHER INFORMATION CONTACT: John W. Pates, Jr., Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8195; email address: pates.john@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides.

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

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. What action is the Agency taking?

This notice announces receipt by the Agency of requests from registrants to cancel 16 pesticide products registered under FIFRA section 3 (7 U.S.C. 136a) or 24(c) (7 U.S.C. 136v(c)). These registrations are listed in sequence by registration number (or company number and FIFRA section 24(c) number) in Table 1 of this unit.

Unless the Agency determines that there are substantive comments that warrant further review of the requests or the registrants withdraw their requests, EPA intends to issue a final order in the **Federal Register** canceling all of the affected registrations.

TABLE 1—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

Registration No.	Product name	Chemical name
000100–00729	Primo® Liquid	Trinexapac-ethyl.
000100–00752	Primo® WSB	Trinexapac-ethyl.
000279–09556	Intruder Residual Cylinder with Cyfluthrin	Piperonyl butoxide, pyrethrins (No inert use), and cyfluthrin.
003546–00041	Shoo-fly Flying Insect Killer	Permethrin, piperonyl butoxide, and pyrethrins (No inert use).
010807–00127	Misty Insect Repellent II	MGK 264, MGK 326, and diethyl toluamide.
046386–00002	Prometrex Technical	Prometryn.
053883–00241	CSI Wipe & Spray Insecticide	Stabilene, piperonyl butoxide, and pyrethrins (No inert use).
053883–00295	CSI Folpet Technical	Folpet.
053883–00301	CSI Folpet MUP	Folpet.
062719–00601	Acetochlor Technical	Acetochlor.
071711–00022	AC 801,757 Miticide-Insecticide	Tebufenpyrad.
071711–00023	AC 801,757 3EC Miticide-Insecticide	Tebufenpyrad.
ME–080001	Nexter	Pyridaben.
PR–130002	IMI 1% G Insecticide	Imidacloprid.
PR–140001	Quali-pro Imidacloprid 1G Nursery & Greenhouse Insecticide.	Imidacloprid.
WA–860025	Drexel Dimethoate 2.67 EC	Dimethoate.

Table 2 of this unit includes the names and addresses of record for all registrants of the products in Table 1 of

this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration

numbers of the products listed in this unit.

TABLE 2—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION

EPA Company No.	Company name and address
100	Syngenta Crop Protection, LLC, 410 Swing Rd., P.O. Box 18300, Greensboro, NC 27419–8300.
279	FMC Corp. Agricultural Products Group, 1735 Market St., RM 1978, Philadelphia, PA 19103.
3546	Lynwood Labs, Inc., 945 Great Plain Ave., Needham, MA 02492–3004.
10807	Amrep, Inc., Agent: Zep, Inc. C/O Compliance Services, 1259 Seaboard Industrial Blvd., NW., Atlanta, GA 30318.
46386	Verolite Chemical Manufacturers, LTD, C/O Makhteshim-Agan of North America, Inc., Agent: Makhteshim-Agan of North America, Inc., 3120 Highwoods Blvd., Suite 100, Raleigh, NC 27604.
53883 PR–130002	Control Solutions, Inc., 5903 Genoa Red Bluff Rd., Pasadena, TX 77507–1041.
62719	Dow Agrosciences, LLC, 9330 Zionsville Rd., 308/2E, Indianapolis, IN 46268–1054.
PR140001	Makhteshim Agan of North America, Inc., D/B/A ADAMA, 3120 Highwoods Blvd., Suite 100, Raleigh, NC 27604.
71711	Nichino America, Inc., Agent: Exponent, Inc., 1150 Connecticut Ave., Suite 1100, Washington, DC 20036.
ME–080001	Gowan Company, P.O. Box 5569, Yuma, AZ 85366.
WA–860025	Drexel Chemical Company, P.O. Box 13327, Memphis, TN 38113–0327.

III. What is the Agency's authority for taking this action?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**.

Section 6(f)(1)(B) of FIFRA (7 U.S.C. 136d(f)(1)(B)) requires that before acting on a request for voluntary cancellation, EPA must provide a 30-day public comment period on the request for voluntary cancellation or use termination. In addition, FIFRA section 6(f)(1)(C) (7 U.S.C. 136d(f)(1)(C)) requires that EPA provide a 180-day comment period on a request for voluntary cancellation or termination of any minor agricultural use before granting the request, unless:

1. The registrants request a waiver of the comment period, or
2. The EPA Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment.

The registrants in Table 2 of Unit II. have requested that EPA waive the 180-day comment period. Accordingly, EPA will provide a 30-day comment period on the proposed requests.

IV. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation should submit such withdrawal in writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. If the products have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling.

V. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products that are currently in the United States and that were packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Because the Agency has identified no significant potential risk concerns associated with these pesticide products, upon cancellation of the products identified in Table 1 of Unit II., EPA anticipates allowing registrants to sell and distribute existing stocks of these products for 1 year after publication of this cancellation order in the **Federal Register**. Thereafter, registrants will be prohibited from selling or distributing

the pesticides identified in Table 1 of Unit II., except for export consistent with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal. Persons other than registrants will generally be allowed to sell, distribute, or use existing stocks until such stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: July 29, 2014.

Richard P. Keigwin, Jr.,
Director, Pesticide Re-Evaluation Division,
Office of Pesticide Programs.

[FR Doc. 2014-18477 Filed 8-5-14; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

[WT Docket No. 05-265; RM-11723; DA 14-997]

Wireless Telecommunications Bureau Seeks Comment on Petition Filed by NTCH, Inc. To Rescind Forbearance and Initiate Rulemaking To Make Inter-Provider Roaming Rates Available

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document seeks comment on a petition to rescind the Commission's forbearance from the requirements of 47 U.S.C. 211 as they apply to Commercial Mobile Radio Service (CMRS) providers and to initiate a rulemaking to make inter-provider roaming rates available.

DATES: Comments are due on or before August 18, 2014, and reply comments are due on or before September 15, 2014.

ADDRESSES: All filings in response to this notice must refer to RM-11723 and WT Docket No. 05-265. The Wireless Telecommunications Bureau strongly encourages interested parties to file comments electronically. Comments may be submitted electronically by the following methods:

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

■ **Federal Communications Commission's Web site:** <http://fjallfoss.fcc.gov/ecfs2/>. Follow the instructions for submitting comments.

■ **By Email:** To obtain instructions for filing by email, filers should send an

email to ecfs@fcc.gov, and include the following words in the body of the message, "get form." A sample form and direction will be sent in response.

■ **Paper Filers:** Parties who choose to file by paper must file an original and one copy of each filing. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Attn: WTB/SCPD, Office of the Secretary, Federal Communications Commission. All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th Street SW., Room TW-A325, Washington, DC 20554. All hand deliveries must be held together with rubber bands or fasteners. All envelopes must be disposed of before entering the building. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW., Washington, DC 20554.

■ In addition, Parties are requested to send one copy of their comments and reply comments to Best Copy and Printing, Inc., Portals II, 445 12th Street SW., Room CY-B402, Washington, DC 20554, (800) 378-3160, email FCC@BCPIWEB.com.

People with Disabilities: Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: FCC504@fcc.gov or phone: 202-418-0530 or TTY: 202-418-0432.

FOR FURTHER INFORMATION CONTACT: Wireless Telecommunications Bureau, Spectrum and Competition Policy Division, William Beckwith at (202) 418-0134 or via email at William.Beckwith@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of public notice (DA 14-997) released on July 14, 2014; the complete text of the public notice is available for public inspection and copying from 8:00 a.m. to 4:30 p.m. Eastern Time (ET) Monday through Thursday or from 8:00 a.m. to 11:30 a.m. ET on Fridays in the FCC Reference Information Center, 445 12th Street SW., Room CY-A257, Washington, DC 20554. The document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc. (BCPI), 445 12th Street SW., Room CY-B402, Washington, DC 20554, telephone 202-488-5300, fax 202-488-5563, or you

may contact BCPI at its Web site: <http://www.BCPIWEB.com>. When ordering documents from BCPI, please provide the appropriate FCC document number, for example, DA 14–997.

On July 2, 2014, NTCH, Inc. (Petitioner), filed a petition seeking Commission action to rescind the blanket forbearance of the rate publication requirement (47 U.S.C. 211) for roaming rates offered by CMRS carriers and to amend 47 CFR 20.15(b) by deleting the CMRS exemption from filing roaming rates, whether for data roaming or voice roaming. Petitioner also asks the Commission to adopt a rule requiring CMRS providers and commercial mobile data service providers to make their roaming rates publicly and openly available online and to prohibit CMRS and commercial mobile data service providers from entering into or enforcing agreements that prevent disclosure of roaming rates. By the public notice that was released on July 14, 2014 (DA 14–997), the Bureau seeks comment on the petition.

This proceeding has been designated as a “permit-but-disclose” proceeding in accordance with the Commission’s *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter’s written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with 47 CFR 1.1206(b). In proceedings governed by 47 CFR 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte*

presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (e.g., .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission’s *ex parte* rules.

Federal Communications Commission.

Nese B. Guendelsberger,
Chief, Spectrum and Competition Policy
Division, Wireless Telecommunications
Bureau.

[FR Doc. 2014–18626 Filed 8–5–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of the Termination of the Receivership of 10071, MetroPacific Bank, Irvine, California

Notice is hereby given that the Federal Deposit Insurance Corporation (“FDIC”) as Receiver for Metro Pacific Bank, Irvine, California (“the Receiver”) intends to terminate its receivership for said institution. The FDIC was appointed receiver of Metro Pacific Bank on June 26, 2009. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 32.1, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: July 30, 2014.

Federal Deposit Insurance Corporation.

Robert E. Feldman,
Executive Secretary.

[FR Doc. 2014–18550 Filed 8–5–14; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreement Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments on the agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. A Copy of the agreement is available through the Commission’s Web site (www.fmc.gov) or by contacting the Office of Agreements at (202) 523–5793 or tradeanalysis@fmc.gov.

Agreement No.: 012290.

Title: Crowley/King Ocean Space Charter and Sailing Agreement—Northern Zone.

Parties: Crowley Latin America Services, LLC and King Ocean Services Limited, Inc.

Filing Party: Wayne Rohde, Esq.; Cozen O’Connor; 1627 I Street NW., Suite 1100; Washington, DC 20006.

Synopsis: The agreement would authorize Crowley to charter space to King Ocean in the trade between the U.S. East Coast, on the one hand, and ports in Guatemala and Honduras, on the other hand. The parties have requested expedited review.

By Order of the Federal Maritime Commission.

Dated: August 1, 2014.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2014–18572 Filed 8–5–14; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

The Commission gives notice that the following applicants have filed an application for an Ocean Transportation Intermediary (OTI) license as a Non-Vessel-Operating Common Carrier (NVO) and/or Ocean Freight Forwarder (OFF) pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. 40101). Notice is also given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) for a licensee.

Interested persons may contact the Office of Ocean Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573, by telephone at (202) 523–5843 or by email at OTI@fmc.gov.

Anchor Group Inc dba Anchor Logistics (NVO), 1395 Bradbury Road, San

Marino, CA 91108, Officers: Chao-Yi Kuo, Vice President (QI), Yong Chen, President, Application Type: New NVO License.

Armada Services, LLC (NVO & OFF), 5520 Research Park Drive, Suite 100, Baltimore, MD 21228, Officer: Katrina N. Dill, Managing Member (QI), Application Type: Name Change to Premium Logistics North America, LLC and QI Change.

DJS International Services, Inc. (NVO & OFF), 4215 Gateway Drive, Suite 100, Colleyville, TX 76034, Officers: Paul F. Sekin, Vice President (QI), David M. Meyer, Vice President (QI), Application Type: Additional QI.

Exel Global Logistics Inc. (NVO & OFF), 22879 Glenn Drive, Suite 100, Sterling, VA 20164, Officers: SueAnn Fulton, President (QI), Cheryl Stewart, Director, Application Type: QI Change.

Goldmar, Corp. (NVO & OFF), 5220 NW 72nd Avenue, Suite #3, Miami, FL 33166, Officers: Enrique J. Chia, Vice President (QI), Valerie Chia, President, Application Type: New NVO & OFF License.

ICA Logistics, Inc. (NVO & OFF), 5803 Sovereign Drive, Suite 216, Houston, TX 77036, Officers: Qadir A. Wakkiluddin, Secretary (QI), Mohammed N. Aliyu, Executive Director, Application Type: New NVO & OFF License.

Inter-American Movers and Forwarders, LLC (OFF), 3032 NW 72nd Avenue, Miami, FL 33122, Officers: Alejandro Jerez, Managing Member (QI), Marcia Bermudez, Member, Application Type: QI Change.

M Forwarder, LLC (NVO & OFF), 161–15 Rockaway Blvd., Suite 209, Jamaica, NY 11434, Officer: Rick C.Y. Ma, Director (QI), Application Type: QI Change.

Oceanika Express Inc. (NVO), 8401 NW 90th Street, Medley, FL 33166, Officers: Benigno Martin, CEO (QI), Luis E. Mendoza, Director, Application Type: New NVO License.

Pinnacle International LLC (NVO & OFF), 115 Collington Place, Madison, AL 35758, Officers: Johnny M. Summers, Manager (QI), John E. Arnold, Manager, Application Type: New NVO & OFF License.

Sapphire Worldwide LLC (NVO & OFF), 5399 SW 155 Avenue, Miramar, FL 33027, Officer: Yolanda Vila, Managing Member (QI), Application Type: New NVO & OFF License.

By the Commission.

Dated: August 1, 2014.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2014–18571 Filed 8–5–14; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Reissuances

The Commission gives notice that the following Ocean Transportation Intermediary licenses have been reissued pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. 40101).

License No.: 016293F.

Name: Japan Express America Inc.

Address: 2203 East Carson Street, Unit A–2, Long Beach, CA 90810.

Date Reissued: June 22, 2014.

License No.: 023771F

Name: Boacon Synergy Inc.

Address: 7933 Mill Creek Circle, West Chester, OH 45069.

Date Reissued: July 6, 2013.

Sandra L. Kusumoto.

Director, Bureau of Certification and Licensing.

[FR Doc. 2014–18574 Filed 8–5–14; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Revocations and Terminations

The Commission gives notice that the following Ocean Transportation Intermediary licenses have been revoked or terminated for the reason indicated pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. 40101) effective on the date shown.

License No.: 004236F.

Name: Torrance Van & Storage Company dba S&M Moving Systems.

Address: 12128 Burke Street, Santa Fe Springs, CA 90670.

Date Revoked: July 18, 2014.

Reason: Failed to maintain a valid bond.

License No.: 016293N.

Name: Japan Express America Inc.

Address: 2203 E. Carson Street, Suite A–2, Long Beach, CA 90810.

Date Revoked: June 22, 2014.

Reason: Failed to maintain a valid bond.

License No.: 016836N.

Name: Xing Ya Shipping LLC.

Address: 27413 Tourney Road, Suite 200, Valencia, CA 91355.

Date Revoked: July 18, 2014.

Reason: Failed to maintain a valid bond.

License No.: 017466N.

Name: Compass Shipping, Inc.

Address: 730 Chester Street, Brooklyn, NY 11236.

Date Revoked: July 11, 2014.

Reason: Failed to maintain a valid bond.

License No.: 018789F.

Name: Cargo Agents, Inc.

Address: 143–30 38th Avenue, Suite 1H, Flushing, NY 11354–5742.

Date Revoked: July 5, 2014.

Reason: Failed to maintain a valid bond.

License No.: 019426N.

Name: TP Express, Inc.

Address: 1370 E. Higgins Road, Elk Grove Village, IL 60007.

Date Surrendered: July 18, 2014.

Reason: Voluntary surrender of license.

License No.: 019792N.

Name: International Specialists Worldwide Moving, Inc.

Address: 5001 South Claiborne, Suite A, New Orleans, LA 70125.

Date Revoked: July 17, 2014.

Reason: Failed to maintain a valid bond.

License No.: 021553N.

Name: Eagle Transport Services Inc.

Address: 181 South Franklin Avenue, Suite 309, Valley Stream, NY 11581.

Date Revoked: July 16, 2014.

Reason: Failed to maintain a valid bond.

License No.: 021239NF.

Name: Spi International

Transportation (U.S.A.) Corp. dba Silver Pacific Global Logistics.

Address: 5205 South 2nd Avenue, Suite A, Everett, WA 98203.

Date Revoked: July 6, 2014 (NVOCC) and July 19, 2014 (OFF).

Reason: Failed to maintain valid bonds.

License No.: 022167N.

Name: American & Caribbean Shipping Inc.

Address: 13 East Tremont Avenue, Bronx, NY 10453.

Date Revoked: July 3, 2014.

Reason: Failed to maintain a valid bond.

License No.: 022729NF.

Name: Caribbean Warehouse & Logistics, Inc.

Address: Royal Industrial Park, Bldg. B, Unit 4, Road 869 KM 1.5, Catano, PR 00918.

Date Revoked: June 11, 2014.

Reason: Failed to maintain valid bonds.

License No.: 023771N.

Name: Boacon Synergy Inc.

Address: 7933 Mill Creek Circle, West Chester, OH 45069.

Date Revoked: July 6, 2013.

Reason: Failed to maintain a valid bond.

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. 2014-18566 Filed 8-5-14; 8:45 am]

BILLING CODE 6730-01-P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board of Governors of the Federal Reserve System (Board) its approval authority under the Paperwork Reduction Act (PRA), pursuant to 5 CFR 1320.16, to approve of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board under conditions set forth in 5 CFR part 1320 Appendix A.1. 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 instruments 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.

DATES: Comments must be submitted on or before October 6, 2014.

ADDRESSES: You may submit comments, identified by *FR Y-9C* or *FR Y-9SP* by any of the following methods:

- *Agency Web site:* <http://www.federalreserve.gov>. Follow the instructions for submitting comments at <http://www.federalreserve.gov/apps/foia/proposedregs.aspx>.

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

- *Email:* regs.comments@federalreserve.gov. Include OMB number in the subject line of the message.

- *Fax:* (202) 452-3819 or (202) 452-3102.

- *Mail:* Robert deV. Frierson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW., Washington, DC 20551.

All public comments are available from the Board's Web site at <http://www.federalreserve.gov/apps/foia/proposedregs.aspx> as submitted, unless modified for technical reasons.

Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper form in Room MP-500 of the Board's Martin Building (20th and C Streets NW.) between 9:00 a.m. and 5:00 p.m. on weekdays.

Additionally, commenters may send a copy of their comments to the 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 or by fax to (202) 395-6974.

FOR FURTHER INFORMATION CONTACT: A copy of the PRA OMB submission, including the proposed reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files, once approved. These documents will also be made available on the Federal Reserve Board's public Web site at: <http://www.federalreserve.gov/apps/reportforms/review.aspx> or may be requested from the agency clearance officer, whose name appears below.

Federal Reserve Board Clearance Officer—Cynthia Ayouch—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.

SUPPLEMENTARY INFORMATION:

Request for Comment on Information Collection Proposals

The following information collections, which are being handled under this delegated authority, have received initial Board approval and are hereby published for comment. At the end of the comment period, the proposed information collections, along with an analysis of comments and recommendations received, will be submitted to the Board for final approval under OMB delegated authority. Comments are invited on the following:

- Whether the proposed collection of information is necessary for the proper performance of the Federal Reserve's functions; including whether the information has practical utility;
- The accuracy of the Federal Reserve's estimate of the burden of the proposed information collection,

including the validity of the methodology and assumptions used;

- Ways to enhance the quality, utility, and clarity of the information to be collected;

- Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

- Estimates of capital or start up costs and costs of operation, maintenance, and purchase of services to provide information.

*Proposal to approve under OMB delegated authority the revision, without extension, of the following reports:*¹

- Report title:* Consolidated Financial Statements for Holding Companies.

Agency form number: FR Y-9C.

OMB control number: 7100-0128.

Frequency: Quarterly.

Reporters: Bank holding companies (BHCs), savings and loan holding companies (SLHCs), and securities holding companies (SHCs) (collectively, "holding companies" (HCs)).

Estimated average hours per response: Non-advanced approaches HCs: 50.84 hours, and advanced approaches HCs: 52.09 hours.

Estimated annual reporting hours: 232,515 hours.

Number of respondents: 1,143.

General description of report: This information collection is mandatory for BHCs (12 U.S.C. 1844(c)(1)(A)). Additionally, 12 U.S.C. 1467a(b)(2)(A) and 1850a(c)(1)(A), respectively, authorize the Federal Reserve to require that SLHCs and supervised SHCs file the FR Y-9C with the Federal Reserve. Confidential treatment is not routinely given to the financial data in this report. However, confidential treatment for the reporting information, in whole or in part, can be requested in accordance with the instructions to the form, pursuant to sections (b)(4), (b)(6), or (b)(8) of FOIA (5 U.S.C. 522(b)(4), (b)(6), and (b)(8)).

Abstract: The FR Y-9C consists of standardized financial statements similar to the Federal Financial Institutions Examination Council (FFIEC) Consolidated Reports of Condition and Income (Call Reports) (FFIEC 031 & 041; OMB No. 7100-0036) filed by commercial banks. It collects consolidated data from HCs and is filed

¹ The family of FR Y-9 reporting forms also contains three other mandatory reports, which are not being revised at this time: The Parent Company Only Financial Statements for Large Holding Companies (FR Y-9LP), The Financial Statements for Employee Stock Ownership Plan Holding Companies (FR Y-9ES), and The Supplement to the Consolidated Financial Statements for Holding Companies (FR Y-9CS).

quarterly by top-tier HCs with total consolidated assets of \$500 million or more. (Under certain circumstances defined in the General Instructions, BHCs under \$500 million may be required to file the FR Y-9C.)

Current Actions: FR Y-9C Schedule HC-R collects regulatory data on (1) tier 1, tier 2, and total capital and regulatory capital ratios (regulatory capital components and ratios portion) and (2) risk-weighted assets (risk-weighted assets portion).² The Federal Reserve proposes to revise the reporting requirements for the risk-weighted assets portion of Schedule HC-R by incorporating the standardized approach consistent with the revised regulatory capital rules.³ Compared to the current schedule, the proposed risk-weighted assets portion of Schedule HC-R would provide a more detailed breakdown of on-balance sheet asset and off-balance sheet item categories, remove the ratings-based approach from the calculation of risk-weighted assets, reflect alternative risk-weighting approaches not reliant on credit ratings, and include an expanded number of risk-weight categories, consistent with the revised regulatory capital rules. The Federal Reserve also proposes to delete current memoranda items 3 through 5 and 7 through 10, as these regulatory capital elements no longer exist under the revised regulatory capital rules.

FR Y-9C Schedule HC-L collects regulatory data on derivatives and off-balance sheet items. The Federal Reserve proposes to revise the reporting requirements for off-balance sheet exposures related to securities lent and borrowed, consistent with the revised regulatory capital rules. Currently, institutions include the amount of securities borrowed in the total amount of all other off-balance sheet liabilities if the amount of securities borrowed is more than 10 percent of total holding company equity capital and disclose the

amount of securities borrowed if that amount is more than 25 percent of total holding company equity capital.

Compared to the current schedule, the proposed changes to Schedule HC-L would require all institutions to report the amount of securities borrowed. In addition, the proposed changes to Schedule HC-L would place the data item for securities borrowed immediately after the data item for securities lent. The revised capital rules require the identification of all securities borrowed and lent. By removing the current reporting thresholds, the proposed changes to Schedule HC-L would meet this need.

BHCs and top-tier SLHCs that are not substantially engaged in insurance or commercial activities⁴ (covered SLHCs), which are subject to consolidated regulatory capital requirements effective January 1, 2015, would begin reporting on the proposed revised Schedule HC-R, Part II, and revised Schedule HC-L starting on March 31, 2015, applying the revised regulatory capital rules.

2. Report Title: Parent Company Only Financial Statements for Small Holding Companies.

Agency form number: FR Y-9SP.

OMB control number: 7100-0128.

Frequency: Semiannually, as of the last calendar day of June and December.

Reporters: BHCs, SLHCs and SHCs with total consolidated assets of less than \$500 million (small BHCs, small SLHCs and small SHCs).

Estimated average hours per response: BHCs: 5.40 hours; SLHCs: 16.20 hours.

Estimated annual reporting hours: 183,894 hours.⁵

Number of respondents: 3,939.

General description of report: This information collection is mandatory for BHCs [12 U.S.C. 1844(c)(1)(A)]. Additionally, 12 U.S.C. 1467a(b)(2)(A) and 1850a(c)(1)(A), respectively, authorize the Federal Reserve to require that SLHCs and supervised SHCs file

the FR Y-9SP with the Federal Reserve. Confidential treatment is not routinely given to the financial data in this report. However, confidential treatment for the reporting information, in whole or in part, can be requested in accordance with the instructions to the form, pursuant to sections (b)(4), (b)(6), or (b)(8) of the Freedom of Information Act (5 U.S.C. 552(b)(4), (b)(6), and (b)(8)).

Abstract: The FR Y-9SP is a parent company only financial statement filed semiannually by smaller HCs. Respondents include HCs with total consolidated assets of less than \$500 million. This form is a simplified or abbreviated version of the FR Y-9LP. This report is designed to obtain basic parent company balance sheet and income data, data on intangible assets, and data on intercompany transactions.

Current Actions: The Federal Reserve proposes to revise the FR Y-9SP reporting requirements to align with the revised regulatory capital rules, which apply to covered SLHCs with total consolidated assets of less than \$500 million (small covered SLHCs). The Federal Reserve proposes to revise Schedule SC-R, Part II, as described above for the FR Y-9C, to collect consolidated risk-weighted assets data for small covered SLHCs. Schedule SC-R, Part II, would collect consolidated risk-weighted assets data from small covered SLHCs and therefore eliminate the need for institutions to file a consolidated FR Y-9C report. Small covered SLHCs would apply the revised regulatory capital rules to report their regulatory capital risk-weighted assets data on the proposed revised Schedule SC-R, Part II, starting on June 30, 2015. Small BHCs with total consolidated assets of less than \$500 million would not be affected by this proposal.

The following table summarizes the proposed reporting criteria for FR Y-9C and FR Y-9SP respondents.

² On January 10, 2014, the Federal Reserve published a final notice (79 FR 1862) in the **Federal Register** pertaining to the Board approval of revised reporting requirements for the regulatory capital components and ratios portion of Schedule HC-R, consistent with the revised regulatory capital rules, and designated the risk-weighted assets portion of Schedule HC-R as Part II. See 78 FR 62204.

³ 78 FR 62018 (Oct. 11, 2013).

⁴ A top-tier SLHC is deemed to be substantially engaged in insurance activities (insurance SLHC) if (1) the top-tier SLHC is an insurance underwriting company (as defined in section 201 of the Dodd Frank Act); or (2) as of June 30 of the previous calendar year it held 25 percent or more of its total consolidated assets in subsidiaries that are insurance underwriting companies (other than assets associated with insurance for credit risk). For

purposes of determining the 25 percent threshold, the SLHC must calculate its total consolidated assets in accordance with generally accepted accounting principles (GAAP), or if the SLHC does not calculate its total consolidated assets under GAAP for any regulatory purpose (including compliance with applicable securities laws), the SLHC may estimate its total consolidated assets, subject to review and adjustment by the Federal Reserve. Thus, insurance SLHCs are not required to complete Schedule HC-R, even if they complete other schedules of FR Y-9C.

A top-tier SLHC is deemed to be substantially engaged in commercial activities (commercial SLHC) if (1) the top-tier SLHC is a grandfathered unitary SLHC as defined in section 10(c)(9)(A) of HOLA and (2) as of June 30 of the previous calendar year it derived 50 percent or more of its total consolidated assets or 50 percent of its total

revenues on an enterprise-wide basis (as calculated under GAAP) from activities that are not financial in nature under section 4(k) of the Bank Holding Company Act (12 U.S.C. 1842(k)). This exclusion from the revised regulatory capital rules is similar to the current regulatory reporting exemption for SLHCs substantially engaged in commercial activities and is designed to capture those SLHCs that would likely be subject to a future intermediate HCs regulation of the Federal Reserve.

⁵ On December 30, 2013, the Federal Reserve approved a revision to the FR Y-9C and FR Y-9SP consistent with the regulatory capital rules approved by the Board of Governors on July 2, 2013. This revision resulted in a one-time implementation cost of 500 hours per respondent, for 271 respondents, with a total increase of 135,500 hours for the FR Y-9SP for 2014.

Respondents	2014	2015
FR Y–9C respondents		
Non-advanced approaches BHCs	• Complete the current Schedule HC–R, Part I.A and Part II. • Do not complete proposed Schedule HC–R, Part I.B.	• Current Schedule HC–R, Part I.A is removed and Part I.B is re-designated as Part I; • Complete the proposed Schedule HC–R, Part I.B (re-designated as Part I in 2015) and Part II; • Schedule HC–R, Part II includes the proposed revised and renumbered risk-weighted assets portion. • Proposed changes to Schedule HC–L would be implemented.
Advanced approaches BHCs	• Do not complete Schedule HC–R, Part I.A (items 1 through 33). • Complete current Schedule HC–R, Part II. • Complete proposed Schedule HC–R, Part I.B (items 1 through 48).	
Covered SLHCs other than small covered SLHCs.	Do not complete Schedule HC–R.	
FR Y–9SP respondents		
Small BHCs	No change	No change Complete proposed Schedule SC–R, Parts I and II.
Small covered SLHCs	No change	

Detailed Description of Proposed Schedules HC–R, Part II and SC–R, Part II

This section describes the proposed changes to FR Y–9C Schedule HC–R, Part II and FR Y–9SP Schedule SC–R, Part II to implement the reporting of risk-weighted assets consistent with the revised regulatory capital rules. As previously discussed, effective for the March 31, 2015, report date, the existing risk-weighted assets portion of Schedule HC–R, Part II (items 34 through 62 and Memoranda items 1 through 11), would be replaced by a revised Part II that would be completed by HCs that file the FR Y–9C. Effective June 30, 2015, the proposed Schedule SC–R, Part II would be completed by covered SLHCs that file the FR Y–9SP.

Proposed revised Part II of Schedules HC–R and SC–R would be divided into the following sections: (A) On-balance sheet asset categories; (B) derivatives and off-balance sheet items; (C) totals; and (D) memoranda items for derivatives. A brief description of each of these sections and the corresponding line items is provided below.

A. Schedules HC–R, Part II and SC–R, Part II, Items 1 Through 11: Balance Sheet Asset Categories

Proposed data items 1 through 8 reflect on-balance sheet asset categories (excluding those assets within each category that meet the definition of a securitization exposure), similar to the asset categories included in the current

version of Schedule HC–R, but the proposed items would capture greater reporting detail. The number of risk weight categories to which the individual assets in each asset category would be allocated would be expanded consistent with the revised regulatory capital rules. On-balance sheet assets and off-balance sheet items that meet the definition of a securitization exposure would be reported in items 9 and 10, respectively. The proposed instructions, with reference to the revised regulatory capital rules, would describe the appropriate risk-weight category allocations for each on-balance sheet asset category and the appropriate risk-weight calculations for securitization exposures.

Subject to the separate reporting of securitization exposures from the related on-balance sheet asset category, total on-balance sheet assets are equal to the sum of: (Item 1) cash and balances due from depository institutions; securities, excluding securitization exposures, which are composed of (item 2.a) held-to-maturity (HTM) securities and (item 2.b) available-for-sale (AFS) securities; (item 3) federal funds sold and securities purchased under agreements to resell; loans and leases held for sale, which are composed of (item 4.a) residential mortgage exposures, (item 4.b) high volatility commercial real estate (HVCRE) exposures, (item 4.c) exposures past due 90 days or more or on nonaccrual, and (item 4.d) all other exposures; loans and

leases, net of unearned income, which are composed of (item 5.a) residential mortgage exposures, (item 5.b) HVCRE exposures, (item 5.c) exposures past due 90 days or more or on nonaccrual, and (item 5.d) all other exposures; less (item 6) allowance for loan and lease losses; (item 7) trading assets, excluding securitization exposures that receive standardized charges; (item 8) all other assets; and on-balance sheet securitization exposures, which are composed of (item 9.a) HTM securities, (item 9.b) AFS securities, (item 9.c) trading assets that receive standardized charges, and (item 9.d) all other on-balance sheet securitization exposures. As mentioned above, off-balance-sheet securitization exposures would be reported in item 10.

Line item 11 would collect total information on the institution's on-balance sheet asset categories and on-balance sheet securitization exposures, including for each risk-weight category, calculated as the sum of items 1 through 9.

B. Schedules HC–R, Part II and SC–R, Part II, Items 12 Through 21: Derivatives and Off-Balance Sheet Items

Proposed data items 12 through 21 pertain to the reporting of derivatives and off-balance sheet items, excluding those that meet the definition of a securitization exposure (which are reported in item 10 as discussed above). Consistent with the revised regulatory capital rules, new data items would be

added and the number of risk weight categories to which the credit equivalent amounts of derivatives and off-balance sheet items would be allocated would be expanded. The proposed instructions, with reference to the revised regulatory capital rules, would describe the appropriate risk-weight category allocations for each derivative and off-balance sheet item category.

Derivatives and off-balance sheet items would consist of: (Item 12) financial standby letters of credit; (item 13) performance standby letters of credit and transaction-related contingent items; (item 14) commercial and similar letters of credit with an original maturity of one year or less; (item 15) retained recourse on small business obligations sold with recourse; (item 16) repo-style transactions (excluding reverse repos), which includes securities borrowed, securities lent, and securities sold under agreements to repurchase; (item 17) all other off-balance sheet liabilities; unused commitments, which is composed of (item 18.a) the unused portion of commitments with an original maturity of one year or less, excluding asset-backed commercial paper (ABCP) conduits, (item 18.b) the unused portion of eligible ABCP liquidity facilities with an original maturity of one year or less, and (item 18.c) the unused portion of commitments and commercial and similar letters of credit that have an original maturity exceeding one year; (item 19) unconditionally cancelable commitments; (item 20) the credit equivalent amount of over-the-counter derivative contracts; and (item 21) the credit equivalent amount of centrally cleared derivative contracts.

C. Schedules HC–R, Part II and SC–R, Part II, Items 22 Through 30: Totals

Proposed data items 22 through 30 apply the risk-weight factors to the exposure amounts reported for total assets, derivatives, and off-balance sheet items in items 11 through 21 and would calculate the HC's total risk-weighted assets.

Data item 24 would collect information on an HC's risk-weighted assets by risk-weight category. For each column, this would be equal to the product of the amount reported (data item 22) for total assets, derivatives, and off-balance sheet items by risk-weight category, multiplied by (data item 23) the applicable risk-weight factor.

Data item 25 would collect an HC's measurement of risk-weighted assets for purposes of calculating the HC's 1.25 percent of risk-weighted assets limit on the allowance for loan and lease losses.

Data item 26 would collect an HC's standardized measurement of market risk-weighted assets, if applicable. However, this item is not applicable to filers of the FR Y–9SP, so it will only appear in Schedule HC–R, Part II.

Data item 30 would collect an HC's total risk-weighted assets, calculated as: (Data item 27) risk-weighted assets before deductions for excess allowance of loan and lease losses and allocated risk transfer reserve; less (data item 28) excess allowance for loan and lease losses; and less (data item 29) allocated transfer risk reserve.

D. Schedules HC–R, Part II and SC–R, Part II, Memoranda Items 1 Through 4: Memoranda

In proposed memorandum items 1 through 3, an HC would report the current credit exposure and notional principal amounts of its derivative contracts. Consistent with the revised regulatory capital rules, existing memorandum item 2 would be revised.

Memorandum item 1 would continue to collect the HC's total current credit exposure amount for all interest rate, foreign exchange rate, gold, credit, commodity, equity, and other derivative contracts covered by the revised regulatory capital rules after considering applicable legally enforceable bilateral netting agreements.

Memoranda items 2 and 3, respectively, would collect, by remaining maturity and type of contract, the notional principal amounts of the HC's over-the-counter and centrally cleared derivative contracts subject to the revised regulatory capital rules. Data on interest rate, foreign exchange rate and gold, credit (investment grade reference assets), credit (non-investment grade reference assets), equity, precious metals (except gold), and other derivative contracts would be reported separately. Currently, HCs report these notional principal amounts and remaining maturities, but without distinguishing between over-the-counter and centrally cleared derivatives. In addition, foreign exchange rate contracts and gold contracts would be combined in Memoranda items 2 and 3, whereas each of these two types of contracts currently is reported separately in Memorandum item 2.

Memoranda item 4 would retain the memoranda item related to standardized market risk equivalent assets attributable to specific risk that is included in the risk-weighted assets portion of current Schedule HC–R without change (current Schedule HC–R, Part II, memoranda item 6). However, this item is not applicable to filers of the

FR Y–9SP, so it will only appear in Schedule HC–R, Part II.

Detailed Description of Proposed Revisions to Schedule HC–L

This section describes the proposed changes to FR Y–9C, Schedule HC–L, to implement the reporting of securities lent and borrowed consistent with the revised regulatory capital rules. Effective for the March 31, 2015, report date, the existing line item for securities lent (current item 6 of Schedule HC–L) would be renumbered and the existing reporting requirements for securities borrowed (current items 9 and 9.a) would be revised as described below.

In current Schedule HC–L, securities lent and borrowed are reported separately, not in sequential order. Furthermore, all institutions must report securities lent, but securities borrowed are reported and disclosed only if the amount exceeds specified thresholds. Securities borrowed are included in data item 9. All other off-balance sheet liabilities, if the amount of securities borrowed is greater than 10 percent of Schedule HC, data item 27.a, Total holding company equity capital. If the amount of securities borrowed is greater than 25 percent of total holding company equity capital, then that amount is reported separately in data item 9.a, Securities borrowed.

Proposed data item 6.a would be used for reporting securities lent and data item 6.b would be used for reporting securities borrowed. The total amount of securities borrowed would be reported in data item 6.b regardless of amount, not just when the amount is more than the 10 percent of the holding company equity capital threshold, as is currently the case.

Board of Governors of the Federal Reserve System, August 1, 2014.

Robert deV. Frierson,
Secretary of the Board.

[FR Doc. 2014–18578 Filed 8–5–14; 8:45 am]

BILLING CODE 6210–01–P

**GENERAL SERVICES
ADMINISTRATION**

[Notice–GTAC–2014–03; Docket No. 2014–0002; Sequence 28]

**Government-Wide Travel Advisory
Committee (GTAC); Public Advisory
Committee Meetings**

AGENCY: Office of Government-wide Policy, General Services Administration (GSA).

ACTION: Notice.

SUMMARY: This Government-wide Travel Advisory Committee (GTAC) (the

Committee) is a Federal Advisory Committee established in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C., App 2. This notice announces the next GTAC meeting, which is open to the public via teleconference and webinar.

DATES: The upcoming GTAC meeting is scheduled for September 23, 2014 and will begin at 9:00 a.m. Eastern Standard Time and end no later than 4:00 p.m. Eastern Standard Time.

FOR FURTHER INFORMATION CONTACT: Ms. Marcerto Barr, Designated Federal Officer (DFO), Government-wide Travel Advisory Committee (GTAC), Office of Government-wide Policy, General Services Administration, 1800 F Street NW., Washington, DC 20405, 202-208-7654 or by email to: gtac@gsa.gov.

SUPPLEMENTARY INFORMATION: The purpose of the GTAC is to conduct public meetings, submit reports and to make recommendations to existing travel policies, processes and procedures, including the per diem methodology to assure that official travel is conducted in a responsible manner with the need to minimize costs.

Authority: The GSA Office of Asset and Transportation Management, Travel and Relocation Division, establishes policy that governs travel by Federal civilian employees and others authorized to travel at Government expense on temporary duty travel through the Federal Travel Regulation (FTR).

Agenda: The meeting will cover Common Carrier, City Pair, and Standard Temporary Duty Travel (en-route) and a follow-up of previous meeting topics.

Meeting Access: The meeting is open to the public via teleconference and webinar. Members of the public wishing to listen in on the GTAC discussion are recommended to visit the GTAC Web site at www.gsa.gov/gtac for the meeting details. However, members of the public wishing to comment on the discussion or topics outlined in the agenda should follow the steps detailed in Procedures for Providing Public Comments.

Availability Of Materials For The Meeting: Please see the GTAC Web site www.gsa.gov/gtac for any available materials and detailed meeting notes after the meeting.

Procedures For Providing Public Comments: In general, public comments will be posted to www.gsa.gov/gtac. Non-electronic documents will be made available for public inspection and copying at GSA, 1800 F Street NW., Washington, DC 20405, on official business days between the hours of 10:00 a.m. Eastern Standard Time and

4:00 p.m. Eastern Standard Time. The public can make an appointment to inspect comments by telephoning the DFO at 202-208-7654. All comments, including attachments and other supporting materials received, are part of the public record and subject to public disclosure. Any comments submitted in connection with the GTAC meeting will be made available to the public under the provisions of the Federal Advisory Committee Act.

The public is invited to submit written comments within seven business days after each meeting by either of the following methods and cite Meeting Notice-GTAC-2014-03.

Electronic or Paper Comments: (1) Submit electronic comments to gtac@gsa.gov; or (2) submit paper comments to the attention of Ms. Marcerto Barr at GSA, 1800 F Street NW., Washington, DC 20405.

Dated: July 31, 2014.

Carolyn Austin-Diggs,

*Acting Deputy Associate Administrator,
Office of Asset and Transportation
Management, Office of Government-wide
Policy.*

[FR Doc. 2014-18556 Filed 8-5-14; 8:45 am]

BILLING CODE 6820-14-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0968]

Draft Guidance for Industry on Upper Facial Lines: Developing Botulinum Toxin Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Upper Facial Lines: Developing Botulinum Toxin Drug Products." The purpose of this draft guidance is to assist sponsors with their clinical trial designs using botulinum toxin drug products intended for the treatment of upper facial lines. This draft guidance clarifies FDA's thinking on endpoint development and clinical trial design considerations for botulinum toxin drug products that present unique safety concerns.

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 November 4, 2014.

ADDRESSES: 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, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, 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.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Cristina Attinello, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5181, Silver Spring, MD 20993-0002, 301-796-3986.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Upper Facial Lines: Developing Botulinum Toxin Drug Products." The purpose of this draft guidance is to assist sponsors with their clinical trial designs using botulinum toxin drug products intended for the treatment of upper facial lines. This draft guidance clarifies FDA's thinking on endpoint development and clinical trial design considerations for botulinum toxin drug products that present unique safety concerns related to the potential for local and distant spread of toxin effect.

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 Agency's current thinking on developing botulinum toxin drug products for upper facial lines. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach 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. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: July 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–18564 Filed 8–5–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0215]

In Vitro Companion Diagnostic Devices; Guidance for Industry and FDA Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “In Vitro Companion Diagnostic Devices.” This guidance is intended to assist sponsors who are planning to develop a therapeutic product for which the use of an in vitro companion diagnostic device is essential for the therapeutic product’s safe and effective use as well as sponsors planning to develop an in vitro companion diagnostic device that is intended to be used with a corresponding therapeutic product.

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: 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 “In Vitro Companion Diagnostic Devices” 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. Alternatively, you may submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, 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 the office that you are ordering from to assist in processing your request.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Mansfield, Center for Devices and Radiologic Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5676, Silver Spring, MD 20993–0002, 301–796–4664; or Christopher Leptak, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 22, Rm. 6462, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–0017; 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

The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry and FDA staff entitled “In Vitro Companion Diagnostic Devices.” This guidance is

intended to assist: (1) Sponsors who are planning to develop a therapeutic product (either a novel product or an existing product with a new indication) for which the use of an in vitro companion diagnostic device (or test) is essential for the therapeutic product’s safe and effective use and (2) sponsors planning to develop an in vitro companion diagnostic device that is intended to be used with a corresponding therapeutic product. The guidance defines “in vitro companion diagnostic device” (also referred to as “IVD companion diagnostic device”) and clarifies that in most circumstances, an IVD companion diagnostic device and its corresponding therapeutic product should be approved or cleared contemporaneously by FDA for the use indicated in the therapeutic product labeling.

Diagnostic tests have been used for many years to enhance the use of therapeutic products. Tests are also used during therapeutic product development to obtain the data FDA uses to make regulatory determinations. After a therapeutic product is commercially available for use, health care professionals may use a relevant diagnostic test, for example, to select the appropriate therapy for a particular patient or to optimize a dosing regimen. Recently, the development of therapeutic products for which the use of a diagnostic test is essential for the products to meet their labeled safety and effectiveness claims has become more common. For example, such a test can identify appropriate subpopulations for treatment or identify populations who should not receive a particular treatment because of an increased risk of a serious side effect. These new technologies are making it increasingly possible to individualize, or personalize, medical therapy by identifying patients who are most likely to respond, or who are at varying degrees of risk for a particular side effect.

FDA believes that use of an IVD companion diagnostic device with a therapeutic product raises important concerns about the safety and effectiveness of both the device and the therapeutic product. An erroneous test result could lead to withholding appropriate therapy or to administering inappropriate therapy. Health care professionals must be able to rely on information from IVD companion diagnostic devices to help make critical treatment decisions. FDA oversight of IVD companion diagnostic devices will help protect patients from treatment risks that could arise from IVD

companion diagnostic devices that have inadequate performance characteristics.

When an appropriate scientific rationale supports such an approach, FDA encourages the joint development of therapeutic products and diagnostic devices that are essential for the safe and effective use of those therapeutic products. To facilitate the development and approval of therapeutic products that are intended for use with IVD companion diagnostic devices, as well as the development of the IVD companion diagnostic devices themselves, FDA is clarifying relevant policies related to these devices and products.

In the **Federal Register** of July 14, 2011 (76 FR 41506), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by October 12, 2011 (76 FR 51993). Thirty two sets of comments were received and reviewed by FDA. The guidance was updated to address comments where appropriate.

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 Agency's current thinking on IVD companion diagnostic devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach 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>, and a search capability for all CDER guidance documents is available at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of "In Vitro Companion Diagnostic Devices," may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1737 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 subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 814, subparts B and E, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR 201.56 and 21 CFR 201.57 have been approved under OMB control number 0910–0572.

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: July 30, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–18538 Filed 8–5–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Gastroenterology and Urology Devices Panel of the Medical Devices 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: Gastroenterology and Urology Devices Panel of the Medical Devices 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 October 1, 2014, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC/North, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900.

Contact Person: Patricio G. Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3628, Silver Spring, MD 20993–0002, Patricio.Garcia@fda.hhs.gov, 301–796–6875, 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: On October 1, 2014, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the SONABlate 450 device sponsored by SonaCare Medical, LLC. The proposed Indication for Use for the SONABlate 450 device, as stated in the PMA, is as follows:

The SONABlate 450 (SONABlate) is intended for use in the treatment of

localized, clinically recurrent prostate cancer after failure of primary external beam radiation therapy.

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 September 16, 2014. 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 September 8, 2014. 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 September 11, 2014.

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 physical disabilities or special needs. If you require special accommodations due to a disability, please contact James Clark at James.Clark@fda.hhs.gov, or 301-796-5293 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: August 1, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014-18616 Filed 8-5-14; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than October 6, 2014.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 10-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Information/Referral and Professional Training Surveys

(OMB No. 0915-xxxx)—[New]

Abstract: These surveys are designed to collect information from recipients of information/referral services and professional training provided by the following two HRSA-funded programs: (1) Traumatic Brain Injury (TBI) State Implementation Partnership Grants and (2) Protection and Advocacy for TBI Grants. Additionally, grant recipients administering these surveys will submit a summary report aggregating the responses from these two surveys.

The authority for this program is the Public Health Service Act, Title XII, Section 1252, as amended (42 U.S.C. 300d-52). Per the authorizing legislation, the intent of these programs is to improve access to rehabilitation and other services regarding traumatic brain injury. The HRSA State Implementation Partnership Grants and State Protection and Advocacy Grants support this charge by providing information to individuals with TBI and their families about TBI, and making referrals to local providers equipped to meet the unique needs of each survivor. Additionally, these grant programs train providers in various settings to identify and effectively serve individuals with TBI and their families.

Individuals with TBI present with a host of different symptoms, which exist with varying levels of severity. Comprehensive, appropriate care often requires a variety of services such as physical rehabilitation, speech rehabilitation, cognitive rehabilitation, special education accommodations, vocational skills coaching, and independent living skills training. These services are often located across many state/local agencies and providers. For this reason, individuals with TBI and their family members often have difficulty identifying local providers with the skills and expertise to deliver services that will promote recovery and maximize independence.

Need and Proposed Use of the Information: HRSA proposes that the data collection surveys be administered by grant recipients to individuals with TBI, their family members, and professional providers for two categories of activities—information/referral services and professional training. These surveys were developed to capture the following: (1) The effectiveness of information and referral services provided to individuals with TBI and their family members, and (2) the effectiveness of training about TBI for professionals who may encounter

individuals with TBI in their work roles. In addition to providing uniform data across these grant programs, the data will help determine what efforts might improve outreach and provision of services for future projects. Grantees will report the data to HRSA in an annual summary report.

Likely Respondents: Individuals with TBI, their family members, and professional providers in various settings will be the likely respondents for these surveys. Recipients of both the

State Implementation Partnership Grants and the Protection and Advocacy Grants programs will be the respondents for the summary report.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying

information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
INITIAL Survey for Individuals with TBI and/or their Family Members Receiving Information and Referral Services from Grant Recipients	7850	1	7850	0.25	1963
FOLLOW-UP Survey for Individuals with TBI and/or their Family Members receiving Information and Referral Services from Grant Recipients	3925	1	3925	0.25	981
INITIAL Survey for Participants in Training Sessions provided by Grant Recipients	13370	1	13370	0.25	3343
FOLLOW-UP Survey for Participants in Training Sessions Provided by Grant Recipients	6685	1	6685	0.25	1671
Summary Report from Grant Recipients	77	1	77	16	1232
Total	31,907		31,907		9190

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Dated: July 28, 2014.

Jackie Painter,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2014-18551 Filed 8-5-14; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Area Health Education Centers (AHEC) Program: Request for Single-Case Deviation

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of Exception from Competition Requirements to Extend

Duration of Grant for Remaining Project Period.

SUMMARY: The Health Resources and Services Administration (HRSA)'s Bureau of Health Workforce is issuing a single-case deviation from competition requirements for the Virginia Health Workforce Development Authority (VHWDA) Area Health Education Center (AHEC) Point of Service Maintenance and Enhancement (POSME) Award (Grant #U77HP26289) to extend the duration of the grant, through August 31, 2017.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Virginia Health Workforce Development Authority (VHWDA).

Amount of Funding Requested through Remaining 3-Year Project Period: \$2,640,543. The estimated award for fiscal year 2014 is approximately \$800,000.

Authority: Section 751 of the Public Health Service Act (42 U.S.C. 294a), as amended by Section 5403 of the Patient Protection and Affordable Care Act, Public Law 111-148.

CFDA Number: 93.107.

Remaining Project Period: September 1, 2014, through August 31, 2017.

Justification: The VHWDA is uniquely qualified to carry out the programmatic activities as described in the approved AHEC work plan for Virginia.

The mission of the VHWDA, as defined in the Code of Virginia, is "to facilitate the development of a statewide health professions pipeline that identifies, educates, recruits, and retains a diverse, appropriately geographically distributed and culturally competent quality workforce.¹ The mission of the Authority is accomplished by: (i) Providing the statewide infrastructure required for health workforce needs assessment and planning that maintains engagement by health professions training programs in decision making and program implementation; (ii) serving as the advisory board and setting priorities for the Virginia Area Health Education Centers Program" The VHWDA's authorizing legislation also includes specific language allowing it to serve as a consortium of medical schools in order to meet the AHEC Program eligibility requirement as outlined in Section 751(b) of the Public Health Service Act.²

There will be no significant change in the scope or objectives of the originally approved project. The same geographic area and population will be served as stated in the original grant. This project timeline is consistent with all other AHEC Program awardees. A full

¹ VA. CODE ANN. § 32.1-122.7:2 (2010).

² 42 U.S.C. 294a(b).

competitive application process for the remaining project period for only one applicant would be a waste of very limited federal resources, and an inefficient and cumbersome process. Additionally, competing a grant to serve the state of Virginia would interrupt and jeopardize the Virginia AHEC Program's approved work plan that has been in progress for almost 2 years. Disrupting this plan would affect the currently established partnerships with medical schools and community partners, which could impact the ability to place students in medically underserved communities, offer health careers enrichment programs, and carryout ongoing data collection and reporting activities.

FOR FURTHER INFORMATION CONTACT:

Jamie Weng, MPH, Project Officer, AHEC Branch, Health Resources and Services Administration, Division of Public Health and Interdisciplinary Education, 5600 Fishers Lane, Room 9C-05, Rockville, Maryland 20857, phone: (301) 443-0186, or email: jweng@hrsa.gov.

Dated: July 29, 2014.

Mary K. Wakefield,
Administrator.

[FR Doc. 2014-18549 Filed 8-5-14; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Direct Service and Contracting Tribes; National Indian Health Outreach and Education II

Announcement Type: New Limited Competition.

Funding Announcement Number: HHS-2014-IHS-NIHOE-0002.

Catalog of Federal Domestic Assistance Number: 93.933.

Key Dates

Application Deadline Date: August 30, 2014.

Review Date: September 8, 2014.

Earliest Anticipated Start Date: September 30, 2014.

Proof of Non-Profit Status Due Date: August 30, 2014.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive applications for two limited competition cooperative agreements under the National Indian Health Outreach and Education (NIHOE) program: The Behavioral

Health—Methamphetamine and Suicide Prevention Intervention (MSPI)/ Domestic Violence Prevention Initiative (DVPI) outreach and education award and the Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) outreach and education award. The Behavioral Health—MSPI/DVPI outreach and education award is funded by IHS and is authorized under the Snyder Act, codified at 25 U.S.C. 13; the Transfer Act, codified at 42 U.S.C. 2001; the Consolidated Appropriations Act, 2014, Public Law 113-76. The HIV/AIDS outreach and education award is funded by the Office of the Secretary (OS), Department of Health and Human Services (HHS). Funding for the HIV/AIDS award will be provided by OS via an Intra-Departmental Delegation of Authority dated May, 29, 2014 to IHS to permit obligation of funding appropriated by the Consolidated Appropriations Act, 2014, Public Law 113-76. Each award is funded through a separate funding stream by each respective Agency's appropriations. The awardee is responsible for accounting for each of the two awards separately and must provide two separate financial reports (one for each award), as indicated below. This program is described in the Catalog of Federal Domestic Assistance under 93.933.

Background

The NIHOE program carries out health program objectives in the American Indian/Alaska Native (AI/AN) community in the interest of improving Indian health care for all 566 Federally-recognized Tribes including Tribal governments operating their own health care delivery systems through Indian Self-Determination and Education Assistance Act (ISDEAA) contracts and compacts with the IHS and Tribes that continue to receive health care directly from the IHS. This program addresses health policy and health programs issues and disseminates educational information to all AI/AN Tribes and villages. The NIHOE MSPI/DVPI and HIV/AIDS awards require that public forums be held at Tribal educational consumer conferences to disseminate changes and updates in the latest health care information. These awards also require that regional and national meetings be coordinated for information dissemination as well as for the inclusion of planning and technical assistance and health care recommendations on behalf of participating Tribes to ultimately inform IHS and the Department of Health and Human Services (HHS) based on Tribal

input through a broad based consumer network.

Purpose

The purpose of these cooperative agreements is to further IHS health program objectives in the AI/AN community with expanded outreach and education efforts for the MSPI/DVPI and HIV/AIDS programs on a national scale and in the interest of improving Indian health care. This announcement includes two separate awards, each of which will be awarded as noted below. The purpose of the MSPI/DVPI award is to further the goals of the national MSPI and national DVPI programs. The MSPI is a national demonstration project aimed at addressing the dual problems of methamphetamine abuse and suicide in Indian Country. The MSPI supports the use and development of evidence-based and practice-based models which are culturally appropriate prevention and treatment approaches to methamphetamine abuse and suicide in a community driven context. The six goals of the MSPI are to effectively prevent, reduce, or delay the use and/or spread of methamphetamine abuse; build on the foundation of prior methamphetamine and suicide prevention and treatment efforts in order to support the IHS, Tribes, and urban Indian health organizations in developing and implementing Tribal and/or culturally appropriate methamphetamine and suicide prevention and early intervention strategies; increasing access to methamphetamine and suicide prevention services; improving services for behavioral health issues associated with methamphetamine use and suicide prevention; promoting the development of new and promising services that are culturally and community relevant; and demonstrating efficacy and impact.

The DVPI is a nationally coordinated community-driven initiative that includes a total of 65 awarded projects. The DVPI promotes the development and implementation of evidence-based and practice-based models of domestic violence prevention that are also culturally competent. The goals of the DVPI are to: Support national and local efforts by the IHS, Tribes, and urban Indian health programs to address domestic and sexual violence (DSV) within AI/AN communities; promote the development and enhancement of culturally appropriate evidence-based and practice-based prevention, treatment, and educational models addressing DSV within AI/AN communities; coordinate services and provide resources for communities to respond to local DSV crises; and

increase access to domestic violence prevention, sexual assault prevention, or treatment services for survivors and their families.

[Note: While the national MSPI/DVPI programs include outreach to urban Indian organizations, outreach aimed specifically at urban Indian organizations will be addressed in a separate award announcement. However, materials developed by the grantee in the (NIHOE-II) MSPI/DVPI award described in this announcement may be distributed by IHS to urban Indian organizations, at the discretion of the Agency.]

The purpose of the HIV/AIDS award is to further the goals of the national HIV/AIDS program. HIV and AIDS are a critical and growing health issue within the AI/AN population. The IHS National HIV/AIDS Program seeks to avoid complacency and to increase awareness of the impact of HIV/AIDS on AI/ANs. All activities are part of the IHS's implementation plan to meet the three goals of the President's National HIV/AIDS Strategy (NHAS) to reduce the number of people who become infected with HIV, increase access to care and optimize health outcomes for people living with HIV, and reduce HIV-related disparities. This population faces additional health disparities that contribute significantly to the risk of HIV transmission such as substance abuse and sexually transmitted infections. Amongst AI/AN people, HIV/AIDS exists in both urban and rural populations (and on or near Tribal lands); however, many of those living with HIV are not aware of their status. These statistics, risk factors, and missed opportunities for screening illuminate the need to go beyond raising awareness about HIV and begin active integration of initiatives that will help routinize HIV services. If the status quo is unchanged, prevalence will continue to increase and AI/AN communities may face an irreversible problem. Therefore, the National HIV/AIDS Program is working to change the way HIV is discussed, to change and improve the way HIV testing is integrated into health services, and to firmly establish linkages and access to care. The IHS HIV/AIDS Program is implemented and executed via an integrated and comprehensive approach through collaborations across multi-health sectors, both internal and external to the agency. It attempts to encompass all types of service delivery 'systems' including IHS/Tribal/Urban facilities. The IHS HIV/AIDS Program is committed to realizing the goals of the President's NHAS and has bridged the objectives and implementation to the IHS HIV/AIDS Strategic Plan.

Limited Competition Justification

Competition for both of the awards included in this announcement is limited to national Indian health care organizations with at least ten years of experience providing education and outreach on a national scale. This limitation ensures that the awardee will have: (1) A national information-sharing infrastructure which will facilitate the timely exchange of information between HHS and Tribes and Tribal organizations on a broad scale; (2) a national perspective on the needs of AI/AN communities that will ensure that the information developed and disseminated through the projects is appropriate, useful and addresses the most pressing needs of AI/AN communities; and (3) established relationships with Tribes and Tribal organizations that will foster open and honest participation by AI/AN communities. Regional or local organizations will not have the mechanisms in place to conduct communication on a national level, nor will they have an accurate picture of the health care needs facing AI/ANs nationwide. Organizations with less experience will lack the established relationships with Tribes and Tribal organizations throughout the country that will facilitate participation and the open and honest exchange of information between Tribes and HHS. With the limited funds available for these projects, HHS must ensure that the education and outreach efforts described in this announcement reach the widest audience possible in a timely fashion, are appropriately tailored to the needs of AI/AN communities throughout the country, and come from a source that AI/ANs recognize and trust. For these reasons, this is a limited competition announcement.

II. Award Information

Type of Award

Cooperative Agreements.

Estimated Funds Available

The total amount of funding identified for the current fiscal year (FY) 2014 is approximately \$250,000 to fund two cooperative agreements for one year; \$150,000 will be awarded for the Behavioral Health—MSPI/DVPI award and \$100,000 will be awarded for the HIV/AIDS award. The amount of funding available for competing awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are

selected for funding under this announcement.

Anticipated Number of Awards

Two awards will be issued under this program announcement. It is the intention of IHS and the Office of the Secretary (OS) that one entity will receive both awards. OS and IHS will concur on the final decision as to who will receive both awards.

Project Period

The project periods for each award will be for one year and will run from September 30, 2014 with completion by September 29, 2015.

Cooperative Agreement

Cooperative agreements awarded by HHS are administered under the same policies as a grant. The funding agencies (IHS and OS) are required to have substantial programmatic involvement in the project during the entire award segment. Below is a detailed description of the level of involvement required for both agencies and the grantee. IHS and OS, through IHS, will be responsible for activities listed under section A and the awardee will be responsible for activities listed under section B as stated:

Substantial Involvement Description for Cooperative Agreement

A. IHS Programmatic Involvement

The IHS assigned program official will monitor the overall progress of the awardee's execution of the requirements of the two awards: IHS award and OS award noted below as well as their adherence to the terms and conditions of the cooperative agreements. This includes providing guidance for required reports, developing of tools, and other products, interpreting program findings, and assisting with evaluations and overcoming any difficulties or performance issues encountered. The IHS assigned program official must approve all presentations, electronic content, and other materials, including mass emails, developed by awardee pursuant to these awards and any supplemental awards prior to the presentation or dissemination of such materials to any party.

(1) Behavioral Health—MSPI/DVPI award:

i. The IHS assigned program official will work in partnership with the awardee to identify and provide presentation topics on MSPI/DVPI for the National Tribal Advisory Committee meetings; the Behavioral Health Work Group; webinars; and IHS Area conference calls.

ii. The IHS assigned program official will work in partnership with the awardee to identify MSPI/DVPI projects in need of technical assistance.

(2) HIV/AIDS award:

IHS staff will provide support for the HIV/AIDS award as follows:

i. The IHS assigned program official will work in partnership with the awardee in all decisions involving strategy, hiring of grantee personnel, deployment of resources, release of public information materials, quality assurance, coordination of activities, training, reports, budgets, and evaluations. Collaboration includes data analysis, interpretation of findings, and reporting.

ii. The IHS assigned program official will work closely with OS and all participating IHS health services/programs, as appropriate, to coordinate award activities.

iii. The IHS assigned program official will coordinate the following for OS and the participating IHS program offices and staff:

- Discussion and release of any and all special grant conditions upon fulfillment.

- Monthly scheduled conference calls.

- Appropriate dissemination of required reports to each participating program.

iv. The IHS will, jointly with the awardee, plan and set an agenda for each of the conferences mentioned in this announcement that:

- Shares the training and/or accomplishments.

- Fosters collaboration amongst the participating program offices, agencies, and/or departments.

- Increases visibility for the partnership between the awardee and the IHS and OS.

v. IHS will provide guidance in addressing deliverables and requirements.

vi. IHS will provide guidance in preparing articles for publication and/or presentations of program successes, lessons learned, and new findings.

vii. IHS will communicate via monthly conference calls, individual or collective site visits, and monthly meetings.

viii. IHS staff will review articles concerning the HHS, OS, and the Agency for accuracy and may, as requested by the awardee, provide relevant articles.

ix. IHS will provide technical assistance to the entity as requested.

x. IHS staff may, at the request of the entity's board, participate on study groups and may recommend topics for analysis and discussion.

B. Grantee Cooperative Agreement Award Activities

The awardee must comply with relevant Office of Management and Budget (OMB) Circular provisions regarding lobbying, any applicable lobbying restrictions provided under other law and any applicable restriction on the use of appropriated funds for lobbying activities.

The awardee is responsible for the following in addition to fulfilling all requirements noted for each award component: Behavioral Health—MSPI/DVPI and HIV/AIDS.

i. To succinctly and independently address the requirements for each of the two awards listed below: Behavioral Health—MSPI/DVPI and HIV/AIDS.

ii. To facilitate a forum or forums at which concerns can be heard that are representative of all Tribal governments in the area of health care policy analysis and program development for each of the two components listed above.

iii. To assure that health care outreach and education is based on Tribal input through a broad-based consumer network involving the Area Indian health boards or health board representatives from each of the 12 IHS Areas.

iv. To establish relationships with other national Indian organizations, professional groups, and Federal, State, and local entities supportive of AI/AN health programs.

v. To improve and expand access for AI/AN Tribal governments to all available programs within the HHS.

vi. To disseminate timely health care information to Tribal governments, AI/AN health boards, other national Indian organizations, professional groups, Federal, State, and local entities.

vii. To provide periodic dissemination of health care information, including publication of a newsletter four times a year that features articles on MSPI/DVPI and HIV/AIDS health promotion/disease/behavioral health prevention activities and models of best or promising practices, health policy, and funding information relevant to AI/AN, etc.

The following schedule of deliverables outlines the requirements necessary to effectuate timely and effective support services to Tribal MSPI/DVPI projects:

Summary of Tasks To Be Performed MSPI/DVPI

- At a minimum, the awardee shall provide Tribal MSPI/DVPI program updates at the National Tribal Advisory Committee meetings and conference

calls; and the Behavioral Health Work Group meetings and conference calls.

- At a minimum, the awardee shall serve as a committee member for the National Action Alliance for Suicide Prevention's American Indian/Alaska Native Task Force.

- The awardee shall participate in MSPI/DVPI Area conference calls requested by the IHS assigned program official. The awardee must be included on the agenda and provide presentations on specific areas of interest identified by the Tribal MSPI/DVPI programs and IHS assigned program official.

Outreach and Education

- The awardee shall provide information and education via multi-media venues, including but not limited to teleconference, webinar workshops, and/or online training modules on topics of particular importance to Tribal MSPI/DVPI projects. The awardee will work with MSPI/DVPI Tribal projects and the IHS assigned program official to identify topics. Topics will be discussed prior to the teleconference or webinar and will be subject to approval from the IHS assigned program official.

PowerPoint slides must be submitted for approval two weeks prior to the presentation and will be made available on the IHS MSPI/DVPI Web sites. Awardee's organizational Web site will link to IHS MSPI/DVPI Web sites.

- The awardee shall conduct workshops and/or presentations including, but not limited to, the successes of the MSPI/DVPI and promising practices and/or best practices of Tribal MSPI/DVPI programs at three national conferences (venue and content of presentations to be agreed upon by the awardee and the IHS assigned program official).

- The awardee shall conduct workshops and/or presentations including, but not limited to the Tribal Law and Order Act (TLOA), Indian Alcohol and Substance Abuse (IASA), the development/implementation of Tribal Action Plans (TAPs), and the Community Readiness Model. The topics and content of all presentations will be discussed and will be subject to approval from the IHS assigned program official. PowerPoint slides must be submitted for approval two weeks prior to the presentation and will be made available on the IHS ASA Web site and other TLOA Web sites, which will be identified. The awardee's organizational Web site will feature a link to the IHS ASA Web site and other TLOA Web sites, which will be identified and submitted to the awardee by DBH staff.

- The awardee shall maintain a booth at identified meetings and conferences

to provide comprehensive information on Tribal MSPI/DVPI programs, curricula, findings, and strategies to local, regional, state, and Federal agencies and organizations.

Technical Assistance

- The awardee shall review progress reports of MSPI/DVPI projects identified by the program official.
- The awardee will develop and maintain orientation materials for MSPI/DVPI projects including but limited to factsheets and guides.
- The awardee will provide training and technical assistance to increase AI/AN specific culture- or tradition-based interventions to be listed on the IHS Best and Promising Practice Registry.
- The awardee will provide training and technical assistance to Tribes to address alcohol and substance abuse issues in AI/AN communities. Training and technical assistance will incorporate collaboration with the IASA Steering Committee and all workgroups to identify topics and content related to the implementation of the TLOA and development of TAPs.
- The awardee will conduct collaborative dialogues for TAP learning communities that address the development/implementation of TAP, including the Community Readiness Model.

Information Sharing

- The awardee shall develop, maintain, and disseminate comprehensive information on Tribal MSPI/DVPI programs, curricula, findings, articles, and strategies to all Tribal MSPI/DVPI programs, and present the information at conference and meeting booths as described above.
- The awardee will provide postings on MSPI/DVPI related information for the IHS MSPI/DVPI Web site.
- The awardee will develop and/or maintain a comprehensive list of evidence-based and practice-based program development and business practice guidelines for use by Tribal MSPI/DVPI programs.
- The awardee will develop and publish a semi-annual MSPI/DVPI newsletter focusing on the impact and outcomes of the MSPI/DVPI projects in Tribal communities.
- The awardee shall act as a resource broker and identify subject matter experts to conduct trainings and technical assistance for implementation of the TLOA.
- The awardee shall develop, maintain, and disseminate information on the TLOA and the development/implementation of TAPs, focusing on

various stages of Community Readiness Models.

- The awardee shall provide quarterly articles for the IASA newsletter focusing on the successful impact and outcomes of TAP projects in Tribal communities, available resources, and funding opportunities.

Reporting

- The awardee shall provide semi-annual reports documenting and describing progress and accomplishment of the activities specified above, attaching any necessary documentation to adequately document accomplishments.
- The awardee shall attend bi-weekly, regularly scheduled, in-person and conference call meetings with the IHS assigned program official team to discuss the awardee's services and MSPI/DVPI related issues. The awardee must provide meeting minutes that highlight the awardee's specific involvement and participation.
- The awardee shall obtain approval from the IHS assigned program official for all PowerPoint presentations, electronic content, and other materials, including mass emails, developed by awardee pursuant to this award and any supplemental awards prior to the presentation or dissemination of such materials to any party, allowing for a reasonable amount of time for IHS review

Deliverables

- Attendance at regularly scheduled meetings between awardee and the IHS assigned program official, evidenced by meeting minutes which highlight the awardee's specific involvement and participation.
- Participation on MSPI/DVPI Area conference calls identified by the IHS assigned program official, evidenced by meeting agenda and minutes as needed.
- Report of outcomes at the following (meeting booths, workshops and/or presentations provided):
 - (a) National Tribal Advisory Committee conference calls and meetings.
 - (b) Behavioral Health Work Group conference calls and meetings. (PowerPoint slides in electronic form and one hard copy are to be submitted to the program official and the IHS assigned program official as required).
 - (c) IHS Area conference calls.
 - (d) IHS Area and national webinars.
 - (e) Other AI/AN national conferences
- Completed programmatic reviews of semi and annual progress reports of Tribal MSPI/DVPI projects in order to identify projects that require technical assistance. [Note: This review is not to

replace IHS review of MSPI/DVPI programs. The programmatic reviews to be conducted by grantee are secondary reviews intended solely to identify programs in need of technical assistance.]

- The awardee shall help the IHS assigned program official identify challenges faced by participating Tribal communities and assist in developing solutions.

- Copies of educational and practice-based information provided to Tribal MSPI/DVPI programs (electronic form and one hard copy).
- Copies of all promotional and educational materials provided to Tribal MSPI/DVPI programs and other projects (electronic form and one hard copy).
- Copies of all promotional materials provided to media and other outlets (electronic form and one hard copy).
- Copies of all articles published (electronic form and one hard copy). Submit semi-annual and annual progress reports to DBH, due no later than 30 days after the reporting cycle, attaching any necessary documentation. For example: meeting minutes, correspondence with Tribal MSPI/DVPI projects, samples of all written materials developed including brochures, news articles, videos, radio and television ads to adequately document accomplishments.
- The awardee will submit a deliverable schedule to the program official no later than 30 days after the start date.

HIV/AIDS

In alignment with the above program and independent from MSPI/DVPI activities (both via fiscal resources and programmatic implementation), the awardee shall:

- Disseminate existing HIV/AIDS messages to AI/AN audiences in a format designed to solicit, collect, and report on community-level feedback and generate discussion regarding the disease and its prevention. This may include electronic and emerging means of communication. At least four distinct audiences (such as women, young people, etc.) will be addressed and engaged. Preference will be given to reaching audiences with the highest HIV burden or potential increases as supported by the NHAS.
- Disseminate existing IHS HIV/AIDS program and other HIV/AIDS training materials to educators, health care providers, and other key audiences. Collect and report on relevant evaluation criteria, including impacts on underlying knowledge, attitudes, or beliefs about HIV acquisition, testing, or treatment.

- Deliver HIV/AIDS technical assistance and activity support program. Engage in documented partnerships with AI/AN communities to expand their capacity relevant to HIV/AIDS education and prevention efforts. Local activity support may include subawards of resources and distribution of incentives to qualified AI/AN-serving community organizations increasing HIV/AIDS education and prevention in their populations. Subaward eligibility standards and management controls will be proposed by the awardee and will be subject to IHS approval. These activities must be conducted in accordance with Federal grant policies and procedures. Awardee will collect and maintain relevant evaluation materials and generate reports that highlight progress towards the President's NHAS goals on the community level and that collect best practices for dissemination to other communities.

- Contribute technical expertise to the IHS HIV/AIDS program and develop formal written documents responding to information requests from the public regarding HIV/AIDS initiatives.

- Develop and launch anti-stigma messaging for at least one audience, coordinated with other local activities to increase HIV screening and increase access to services, or increase positive role modeling for people living with, or at risk of, acquiring HIV/AIDS.

- Support and document issue-specific discussions with Tribal Leaders as needed to address effective prevention interventions for AI/AN populations as noted in the President's NHAS.

- Obtain approval from the IHS assigned program official of all presentations, electronic content, and other materials, including mass emails, developed by awardee pursuant to this award and any supplemental awards prior to the presentation or dissemination of such materials to any party, allowing for a reasonable amount of time for IHS review.

III. Eligibility Information

1. Eligibility

To be eligible for this "New/Competing Continuation Limited Competition Announcement", an applicant must:

Provide proof of non-profit status with the application, e.g. 501(c)(3). Eligible applicants that can apply for this funding opportunity are national Indian organizations.

The national Indian organization must have the infrastructure in place to accomplish the work under the proposed program. Eligible entities must

have demonstrated expertise in the following areas:

- Representing all Tribal governments and providing a variety of services to Tribes, Area health boards, Tribal organizations, and Federal agencies, and playing a major role in focusing attention on Indian health care needs, resulting in improved health outcomes for AI/ANs.

- Promotion and support of Indian education and coordinating efforts to inform AI/AN of Federal decisions that affect Tribal government interests including the improvement of Indian health care.

- National health policy and health programs administration.

- Have a national AI/AN constituency and clearly support critical services and activities within the IHS mission of improving the quality of health care for AI/AN people.

- Portray evidence of their solid support of improved health care in Indian Country.

- Provide evidence of at least ten years of experience providing education and outreach on a national scale.

[**Note:** Please refer to Section IV.2 (Application and Submission Information/Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required such as Tribal resolutions, proof of non-profit status, etc.]

A standard term and condition of award will be included in the final Notice of Award (NOA); all grant recipients will be subject to a term and condition that instructs grantees to recognize any same-sex marriage legally entered into in a U.S. jurisdiction that recognizes their marriage, including one of the 50 states, the District of Columbia or a U.S. territory, or in a foreign country so long as that marriage would also be recognized by a U.S. jurisdiction, when applying the terms of the Federal statute(s) governing their awards. This applies regardless of whether or not the couple resides in a jurisdiction that recognizes same-sex marriage. However, this does not apply to registered domestic partnerships, civil unions or similar formal relationships recognized under the law of the jurisdiction of celebration as something other than a marriage. Accordingly, recipients must review and revise, as needed, any policies and procedures which interpret or apply Federal statutory or regulatory references to such terms as "marriage," "spouse," "family," "household member," or similar references to familial relationship to reflect inclusion of same-sex spouses and marriages. Any

similar familial terminology references in HHS statutes, regulations, or policy transmittals will be interpreted to include same-sex spouses and marriages legally entered into as described herein.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

If application budgets exceed the highest dollar amount outlined under the "Estimated Funds Available" section within this funding announcement, the application will be considered ineligible and will not be reviewed for further consideration. If deemed ineligible, IHS will not return the application. The applicant will be notified by email by the Division of Grants Management (DGM) of this decision.

[**Note:** Please refer to Section IV.2 (Application and Submission Information/Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required such as Tribal resolutions, proof of non-profit status, etc.]

Proof of Non-Profit Status

Organizations claiming non-profit status must submit proof. A copy of the 501(c)(3) Certificate must be received with the application submission by the Application Deadline Date listed under the Key Dates section on page one of this announcement.

An applicant submitting any of the above additional documentation after the initial application submission due date is required to ensure the information was received by the IHS by obtaining documentation confirming delivery (i.e. FedEx tracking, postal return receipt, etc.).

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement can be found at <http://www.Grants.gov> or https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_funding

Questions regarding the electronic application process may be directed to Mr. Paul Gettys at (301) 443-2114.

2. Content and Form Application Submission

Two complete separate signed applications are required. Both applications should address all the following components separately in each application. Each separate

application must include the project narrative as an attachment to the application package. Mandatory documents for all applicants include:

- Table of contents.
 - Abstract (one page) summarizing the project.
 - Application forms:
 - SF-424, Application for Federal Assistance.
 - SF-424A, Budget Information—Non-Construction Programs.
 - SF-424B, Assurances—Non-Construction Programs.
 - Budget Justification and Narrative (must be single spaced and not exceed five pages).
 - Project Narrative (must not exceed 20 pages).
 - Background information on the organization.
 - Proposed scope of work, objectives, and activities that provide a description of what will be accomplished, including a one-page Timeframe Chart.
 - Letter of Support from Organization's Board of Directors.
 - 501(c)(3) Certificate.
 - Position Descriptions for all key personnel.
 - Resumes for all key personnel.
 - Contractor/Consultant resumes or qualifications and scope of work.
 - Disclosure of Lobbying Activities (SF-LLL).
 - Certification Regarding Lobbying (GG-Lobbying Form).
 - Copy of current Negotiated Indirect Cost rate (IDC) agreement (required) in order to receive IDC.
 - Organizational Chart (optional).
 - Documentation of current Office of Management and Budget (OMB) A-133 required Financial Audit (if applicable)
- Acceptable forms of documentation include:
- Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
 - Face sheets from audit reports.
- These can be found on the FAC Web site: <http://harvester.census.gov/sac/dissemin/accessoptions.html?submit=Go+To+Database>

Public Policy Requirements

All Federal-wide public policies apply to IHS grants and cooperative agreements with exception of the Discrimination policy.

Requirements for Project and Budget Narratives

A. Project Narrative: This narrative should be a separate Word document that is no longer than 20 pages and must: be single-spaced, be type written, have consecutively numbered pages, use black type not smaller than 12

characters per one inch, and be printed on one side only of standard size 8 1/2" x 11" paper.

Be sure to succinctly address and answer all questions listed under each part of the narrative and place all responses and required information in the correct section (noted below), or they shall not be considered or scored. These narratives will assist the Objective Review Committee (ORC) in becoming more familiar with the applicant's activities and accomplishments prior to this grant award. If the narrative exceeds the page limit, only the first 20 pages will be reviewed. The 20-page limit for the narrative does not include the work plan, standard forms, Tribal resolutions, table of contents, budget, budget justifications, narratives, and/or other appendix items.

There are three parts to the narrative: Part A—Program Information; Part B—Program Planning and Evaluation; and Part C—Program Report. See below for additional details about what must be included in the narrative.

Reminder: You are required to submit two separate complete and signed application packages. One for the Behavioral Health—MSPI/DVPI cooperative agreement and one complete signed application package for the HIV/AIDS cooperative agreement. This applies to the narratives and budgets as well and all components listed below. Be sure to address each component separately in its respective application package. The page limitations below are for each narrative and budget submitted.

Part A: Program Information (6 Page Limitation)

Section 1: Needs

Describe how the national Indian organization has the experience to provide outreach and education efforts regarding the pertinent changes and updates in health care for each of the two components listed herein: Behavioral Health—MSPI/DVPI and HIV/AIDS.

Part B: Program Planning and Evaluation (6 Page Limitation)

Section 1: Program Plans

Describe fully and clearly how the national Indian organization plans to address the NIHOE II MSPI/DVPI and HIV/AIDS requirements, including how the national Indian organization plans to demonstrate improved health education and outreach services to all 566 Federally-recognized Tribes for each of the two components described herein.

Section 2: Program Evaluation

Describe fully and clearly how the outreach and education efforts will impact changes in knowledge and awareness in Tribal communities regarding both components. Identify anticipated or expected benefits for the Tribal constituency.

Part C: Program Report (3 Page Limitation)

Section 1: Describe Major Accomplishments Over the last 24 Months

Identify and describe significant program achievements associated with the delivery of quality health outreach and education. Provide a comparison of the actual accomplishments to the goals established for the project period for both components, or if applicable, provide justification for the lack of progress.

Section 2: Describe Major Activities Over the Last 24 Months

Identify and summarize recent major health related outreach and education project activities of the work performed for both components during the last project period.

B. Budget Narrative: This narrative must include a line item budget with a narrative justification for all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative. Budget should match the scope of work described in the project narrative. The page limitation should not exceed five pages.

3. Submission Dates and Times

Applications must be submitted electronically through Grants.gov by 12:00 a.m., midnight Eastern Daylight Time (EDT) on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Any application received after the application deadline will not be accepted for processing, nor will it be given further consideration for funding. Grants.gov will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the electronic application process, contact Grants.gov Customer Support via email to support@grants.gov or at (800) 518-4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Mr. Paul Gettys, DGM (Paul.Gettys@ihs.gov) at (301) 443-2114. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do

not contact the DGM until you have received a Grants.gov tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

If the applicant needs to submit a paper application instead of submitting electronically via Grants.gov, a waiver must be requested. Prior approval must be requested and obtained from Ms. Tammy Bagley, Acting Director of DGM, (see Section IV.6 below for additional information). The waiver must: (1) Be documented in writing (emails are acceptable), *before* submitting a paper application and (2) include a clear justification for the need to deviate from the required electronic grants submission process. Written waiver request can be sent to GrantsPolicy@ihs.gov with a copy sent to Tammy.Bagley@ihs.gov. Once the waiver request has been approved, the applicant will receive a confirmation of approval and the mailing address to submit the application. Paper applications that are submitted without a copy of the signed waiver from the Acting Director of the DGM will not be reviewed or considered further for funding. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Paper applications must be received by the DGM no later than 5:00 p.m., EDT, on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and appropriate indirect costs.
- Only one grant/cooperative agreement will be awarded per applicant.
- IHS will not acknowledge receipt of applications.

6. Electronic Submission Requirements

All applications must be submitted electronically. Please use the <http://www.Grants.gov> Web site to submit an application electronically and select the "Find Grant Opportunities" link on the homepage. Download a copy of the application package, complete it offline, and then upload and submit the completed application via the <http://www.Grants.gov> Web site. Electronic copies of the application may not be submitted as attachments to email

messages addressed to IHS employees or offices.

If the applicant receives a waiver to submit paper application documents, they must follow the rules and timelines that are noted below. The applicant must seek assistance at least ten days prior to the Application Deadline Date listed in the Key Dates section on page one of this announcement.

Applicants that do not adhere to the timelines for System for Award Management (SAM) and/or <http://www.Grants.gov> registration or fail to request timely assistance with technical issues will not be considered for a waiver to submit a paper application.

Please be aware of the following:

- Please search for the application package in <http://www.Grants.gov> by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application electronically, please contact Grants.gov Support directly at: support@grants.gov or (800) 518-4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).

• Upon contacting Grants.gov, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.

• If it is determined that a waiver is needed, the applicant must submit a request in writing (emails are acceptable) to GrantsPolicy@ihs.gov with a copy to Tammy.Bagley@ihs.gov. Please include a clear justification for the need to deviate from the standard electronic submission process.

- If the waiver is approved, the application should be sent directly to the DGM by the Application Deadline Date listed in the Key Dates section on page one of this announcement.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through Grants.gov as the registration process for SAM and Grants.gov could take up to fifteen working days.

• Please use the optional attachment feature in Grants.gov to attach additional documentation that may be requested by the DGM.

• All applicants must comply with any page limitation requirements described in this Funding Announcement.

• After electronically submitting the application, the applicant will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov

tracking number. The DGM will download the application from Grants.gov and provide necessary copies to the appropriate agency officials. Neither the DGM nor the Office of Direct Service and Contracting Tribes (ODSCT) will notify the applicant that the application has been received.

- Email applications will not be accepted under this announcement.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

All IHS applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B which uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access it through <http://fedgov.dnb.com/webform>, or to expedite the process, call (866) 705-5711.

All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended ("Transparency Act"), to report information on subawards. Accordingly, all IHS grantees must notify potential first-tier subrecipients that no entity may receive a first-tier subaward unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that were not registered with Central Contractor Registration and have not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM home page at <https://www.sam.gov> (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2-5 weeks to become active). Completing and submitting the registration takes approximately one hour to complete and SAM registration will take 3-5 business days to process. Registration with the SAM is free of charge. Applicants may register online at <https://www.sam.gov>.

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, can be found on the

IHS Grants Management, Grants Policy
Web site: https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_policy_topics.

V. Application Review Information

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The 20 page narrative should include only the first year of activities and should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 60 points is required for funding. Points are assigned as follows:

1. Criteria

A. Introduction and Need for Assistance (15 Points)

(1) Describe the organization's current health, education and technical assistance operations as related to the broad spectrum of health needs of the AI/AN community. Include what programs and services are currently provided (i.e., Federally-funded, State-funded, etc.), and identify any memorandums of agreement with other national, Area or local Indian health board organizations. This could also include HHS' agencies that rely on the applicant as the primary gateway organization that is capable of providing the dissemination of health information to Tribes. Include information regarding technologies currently used (i.e., hardware, software, services, Web sites, etc.), and identify the source(s) of technical support for those technologies (i.e., in-house staff, contractors, vendors, etc.). Include information regarding how long the applicant has been operating and its length of association/partnerships with Area health boards, etc. [historical collaboration].

(2) Describe the organization's current technical assistance ability. Include what programs and services are currently provided, programs and services projected to be provided, and describe any memorandums of agreement with other national Indian organizations that deem the applicant as the primary source of health policy information for AI/ANs, or any other memorandums of agreement with other Area Indian health boards, etc.

(3) Describe the population to be served by the proposed projects. Are they hard to reach? Are there barriers? Include a description of the number of Tribes who currently benefit from the technical assistance provided by the applicant.

(4) Describe the geographic location of the proposed project including any geographic barriers experienced by the recipients of the technical assistance to the health care information provided.

(5) Identify all previous IHS cooperative agreement awards received, dates of funding and summaries of the projects' accomplishments. State how previous cooperative agreement funds facilitated education, training and technical assistance nationwide for AI/ANs. (Copies of reports will not be accepted.)

(6) Describe collaborative and supportive efforts with national, Area, and local Indian health boards.

(7) Explain the need/reason for the proposed projects by identifying specific gaps or weaknesses in services or infrastructure that will be addressed by the proposed projects. Explain how these gaps/weaknesses have been assessed.

(8) Explain what measures were taken or will be taken to ensure the proposed projects will not create new gaps or weaknesses in services or infrastructure.

(9) Describe the effect of the proposed project on current programs (i.e., Federally-funded, State funded, etc.) and, if applicable, on current equipment (i.e., hardware, software, services, etc.). Include the effect of the proposed projects on planned/anticipated programs and/or equipment.

(10) Describe how the projects relate to the purpose of the cooperative agreement by identifying how the proposed project will address national Indian health care outreach and education regarding various health data listed, e.g. MSPI/DVPI and HIV and AIDS, dissemination, training, and technical assistance, etc.

B. Project Objective(s), Work Plan and Approach (40 points)

(1) Identify the proposed project objective(s) for each of the two projects, as applicable, addressing the following:

- Measurable and (if applicable) quantifiable.

- results oriented.
- time-limited.

Example: Issue four quarterly newsletters, provide alerts and quantify number of contacts with Tribes. Goals must be clear and concise.

(2) Address how the proposed projects will result in change or improvement in program operations or

processes for each proposed project objective for the selected projects. Also address what tangible products, if any, are expected from the project, (i.e. legislative analysis, policy analysis, annual conferences, mid-year conferences, summits, etc.).

(3) Address the extent to which the proposed projects will provide, improve, or expand services that address the need(s) of the target population. Include a strategic plan and business plan currently in place that are being used that will include the expanded services. Include the plan(s) with the application submission.

(4) Submit a work plan in the Appendix that:

- Provides the action steps on a timeline for accomplishing each of the projects' proposed objective(s).
 - Identifies who will perform the action steps.
 - Identifies who will supervise the action steps taken.
 - Identifies what tangible products will be produced during and at the end of the proposed project objective(s).
 - Identifies who will accept and/or approve work products during the duration of the proposed projects and at the end of the proposed projects.
 - Identifies any training that will take place during the proposed projects and who will be attending the training.
 - Identifies evaluation activities proposed in the work plans.
- (5) If consultants or contractors will be used during the proposed project, please include the following information in their scope of work (or note if consultants/contractors will not be used):
- Educational requirements.
 - Desired qualifications and work experience.
 - Expected work products to be delivered on a timeline.

If a potential consultant/contractor has already been identified, please include a resume in the Appendix.

(6) Describe what updates will be required for the continued success of the proposed project. Include when these updates are anticipated and where funds will come from to conduct the update and/or maintenance.

C. Program Evaluation (20 points)

Each proposed objective requires an evaluation component to assess its progress and ensure its completion. Also, include the evaluation activities in the work plan.

Describe the proposed plan to evaluate both outcomes and process. Outcome evaluation relates to the results identified in the objectives, and process evaluation relates to the work plan and activities of the project.

(1) For outcome evaluation, describe:

- What will the criteria be for determining success of each objective?
- What data will be collected to determine whether the objective was met?

- At what intervals will data be collected?

- Who will collect the data and their qualifications?

- How will the data be analyzed?
- How will the results be used?

(2) For process evaluation, describe:

- How will the projects be monitored and assessed for potential problems and needed quality improvements?

- Who will be responsible for monitoring and managing project improvements based on results of ongoing process improvements and what are their qualifications?

- How will ongoing monitoring be used to improve the projects?

- Describe any products, such as manuals or policies, that might be developed and how they might lend themselves to replication by others.

- How will the organization document what is learned throughout the projects' grant periods?

(3) Describe any evaluation efforts planned after the grant period has ended.

(4) Describe the ultimate benefit to the AI/AN population served by the applicant organization that will be derived from these projects.

D. Organizational Capabilities, Key Personnel and Qualifications (15 points)

This section outlines the broader capacity of the organization to complete the project outlined in the work plan. It includes the identification of personnel responsible for completing tasks and the chain of responsibility for successful completion of the projects outlined in the work plans.

(1) Describe the organizational structure of the organization beyond health care activities, if applicable.

(2) Describe the ability of the organization to manage the proposed projects. Include information regarding similarly sized projects in scope and financial assistance, as well as other cooperative agreements/grants and projects successfully completed.

(3) Describe what equipment (i.e., fax machine, phone, computer, etc.) and facility space (i.e., office space) will be available for use during the proposed projects. Include information about any equipment not currently available that will be purchased through the cooperative agreement/grant.

(4) List key personnel who will work on the projects. Include title used in the work plans. In the Appendix, include

position descriptions and resumes for all key personnel. Position descriptions should clearly describe each position and duties, indicating desired qualifications and experience requirements related to the proposed project. Resumes must indicate that the proposed staff member is qualified to carry out the proposed project activities. If a position is to be filled, indicate that information on the proposed position description.

(5) If personnel are to be only partially funded by this cooperative agreement, indicate the percentage of time to be allocated to this project and identify the resources used to fund the remainder of the individual's salary.

E. Categorical Budget and Budget Justification (10 points)

This section should provide a clear estimate of the program costs and justification for expenses for the entire cooperative agreement period for each award. The budgets and budget justifications should be consistent with the tasks identified in the work plans. Because each of the two awards included in this announcement are funded through separate funding streams, the applicant must provide a separate budget and budget narrative for each of the two components and must account for costs separately.

(1) Provide a categorical budget for each of the 12-month budget periods requested for each of the two projects.

(2) If IDC are claimed, indicate and apply the current negotiated rate to the budget. Include a copy of the rate agreement in the Appendix. *See Section VI. Award Administration Information, 3. Indirect Costs.*

(3) Provide a narrative justification explaining why each line item is necessary or relevant to the proposed project. Include sufficient costs and other details to facilitate the determination that the cost is allowable (i.e., equipment specifications, etc.).

Appendix Items

- Work plan, logic model and/or time line for proposed objectives.

- Position descriptions for key staff.

- Resumes of key staff.

- Consultant or contractor proposed scope of work and letter of commitment (if applicable).

- Current Indirect Cost Agreement.

- Organizational chart.

- Additional documents to support narrative (i.e. data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened by the DGM staff for eligibility and

completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria in this funding announcement. The ORC could be composed of both Tribal and Federal reviewers appointed by the IHS program to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. Applicants will be notified by DGM, via email, to outline minor missing components (i.e., budget narratives, audit documentation, key contact form) needed for an otherwise complete application. All missing documents must be sent to DGM on or before the due date listed in the email of notification of missing documents required.

To obtain a minimum score for funding by the ORC, applicants must address all program requirements and provide all required documentation.

VI. Award Administration Information

1. Award Notices

The Notice of Award (NoA) is a legally binding document signed by the Grants Management Officer and serves as the official notification of the grant award. The NoA will be initiated by the DGM in our grant system, GrantSolutions (<https://www.grantsolutions.gov>). Each entity that is approved for funding under this announcement will need to request or have a user account in GrantSolutions in order to retrieve their NoA. The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period.

Disapproved Applicants

Applicants who received a score less than the recommended funding level for approval, 60 points, and were deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC outlining the weaknesses and strengths of their application submitted. The IHS program office will also provide additional contact information as needed to address questions and concerns as well as provide technical assistance if desired.

Approved But Unfunded Applicants

Approved but unfunded applicants that met the minimum scoring range and were deemed by the ORC to be "Approved," but were not funded due to lack of funding, will have their applications held by DGM for a period of one year. If additional funding becomes available during the course of FY 2014, the approved application may be re-considered by the awarding program office for possible funding. The applicant will also receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC.

Note: Any correspondence other than the official NoA signed by an IHS Grants Management Official announcing to the Project Director that an award has been made to their organization is not an authorization to implement their program on behalf of IHS.

2. Administrative Requirements

Cooperative agreements are administered in accordance with the following regulations, policies, and OMB cost principles:

A. The criteria as outlined in this Program Announcement.

B. Administrative Regulations for Grants:

- 45 CFR part 92, Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local and Tribal Governments.
- 45 CFR part 74, Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, and other Non-profit Organizations.

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

- 2 CFR part 225—Cost Principles for State, Local, and Indian Tribal Governments (OMB Circular A-87).
- 2 CFR part 230—Cost Principles for Non-Profit Organizations (OMB Circular A-122).

E. Audit Requirements:

- OMB Circular A-133, Audits of States, Local Governments, and Non-Profit Organizations.

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of IDC in their grant application. In accordance with HHS Grants Policy Statement, Part II-27, IHS requires applicants to obtain a current IDC rate agreement prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current

rate covers the applicable grant activities under the current award's budget period. If the current rate is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to the DGM.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) <https://rates.psc.gov/> and the Department of Interior (Interior Business Center) http://www.doi.gov/ibc/services/Indirect_Cost_Services/index.cfm. For questions regarding the indirect cost policy, please call (301) 443-5204 to request assistance.

4. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Reports must be submitted electronically via GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Separate progress reports are required for each of the two awards included in this announcement. Program progress reports are required semi-annually, within 30 days after the budget period ends. These reports must include a brief comparison of actual accomplishments to the goals established for the period, or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of expiration of the budget/project period.

B. Financial Reports

Separate financial reports are required for each of the two awards included in

this announcement. The awardee is responsible for accounting for each award separately. Federal Financial Report FFR (SF-425), Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services, HHS at: <http://www.dpm.psc.gov>. It is recommended that the applicant also send a copy of the FFR (SF-425) report to the Grants Management Specialist. Failure to submit timely reports may cause a disruption in timely payments to the organization.

Grantees are responsible and accountable for accurate information being reported on all required reports: The Progress Reports and Federal Financial Report.

C. Federal Subaward Reporting System (FSRS)

This award may be subject to the Transparency Act subaward and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards.

IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a \$25,000 subaward obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the project period is made up of more than one budget period) and where: (1) The project period start date was October 1, 2010 or after and (2) the primary awardee will have a \$25,000 subaward obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting. For the full IHS award term implementing this requirement and additional award applicability information, visit the Grants Management Grants Policy Web site at: https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_policy_topics.

Telecommunication for the hearing impaired is available at: TTY (301) 443-6394.

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Mr. Chris Buchanan, Director, ODSCT, 801 Thompson Avenue, Suite 220, Rockville, Maryland 20852, Telephone: (301) 443-1104, Fax: (301) 443-4666, E-Mail: Chris.Buchanan@ihs.gov.

2. Questions on grants management and fiscal matters may be directed to: Mr. John Hoffman, DGM, Grants Management Specialist, 801 Thompson Avenue, TMP Suite 360, Rockville, Maryland 20852, Telephone: (301) 443-2116, Fax: (301) 443-9602, E-Mail: John.Hoffman@ihs.gov.

3. Questions on systems matters may be directed to: Mr. Paul Gettys, Grant Systems Coordinator, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852, Phone: (301) 443-2114; or the DGM main line (301) 443-5204, Fax: (301) 443-9602, E-Mail: Paul.Gettys@ihs.gov.

VIII. Other Information

The Public Health Service strongly encourages all cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Dated: July 19, 2014.

Yvette Roubideaux,

Acting Director, Indian Health Service.

[FR Doc. 2014-18531 Filed 8-5-14; 8:45 am]

BILLING CODE 4165-16-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2014-0151]

Collection of Information Under Review by Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding the Information Collection Request (ICR), abstracted below, to the Office of

Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of a revision to the following collection of information: 1625-0036, Plan Approval and Records for U.S. and Foreign Tank Vessels Carrying Oil in Bulk. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before September 5, 2014.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG-2014-0151] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT) and/or to OIRA. To avoid duplicate submissions, please use only one of the following means:

(1) *Online:* (a) To Coast Guard docket at <http://www.regulations.gov>. (b) To OIRA by email via: OIRA-submission@omb.eop.gov.

(2) *Mail:* (a) DMF (M-30), DOT, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001. (b) To OIRA, 725 17th Street NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.

(3) *Hand Delivery:* To DMF address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(4) *Fax:* (a) To DMF, 202-493-2251. (b) To OIRA at 202-395-6566. To ensure your comments are received in a timely manner, mark the fax, attention Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of the docket and will be available for inspection or copying at room W12-140 on the West Building Ground Floor, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find the docket on the Internet at <http://www.regulations.gov>.

Copies of the ICR are available through the docket on the Internet at <http://www.regulations.gov>. Additionally, copies are available from: COMMANDANT (CG-612), ATTN: PAPERWORK REDUCTION ACT MANAGER, US COAST GUARD, 2703 MARTIN LUTHER KING JR AVE SE., STOP 7710, WASHINGTON DC 20593-7710.

FOR FURTHER INFORMATION CONTACT:

Contact Mr. Anthony Smith, Office of Information Management, telephone 202-475-3532 or fax 202-372-8405, for questions on these documents. Contact Ms. Cheryl Collins, Program Manager, Docket Operations, 202-366-9826, for questions on the docket.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether these ICRs should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG 2014-0151], and must be received by September 5, 2014. We will post all comments received, without change, to <http://www.regulations.gov>. They will include any personal information you provide. We have an agreement with DOT to use their DMF. Please see the "Privacy Act" paragraph below.

Submitting Comments

If you submit a comment, please include the docket number [USCG-2014-0151]; indicate the specific section of the document to which each comment applies, providing a reason for each comment. You may submit your

comments and material online (via <http://www.regulations.gov>), by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via www.regulations.gov, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the DMF. We recommend you include your name, mailing address, an email address, or other contact information in the body of your document so that we can contact you if we have questions regarding your submission.

You may submit comments and material by electronic means, mail, fax, or delivery to the DMF at the address under **ADDRESSES**, but please submit them by only one means. To submit your comment online, go to <http://www.regulations.gov>, and type "USCG-2014-0151" in the "Search" box. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and will address them accordingly.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this Notice as being available in the docket, go to <http://www.regulations.gov>, click on the "read comments" box, which will then become highlighted in blue. In the "Search" box insert "USCG-2014-0151" and click "Search." Click the "Open Docket Folder" in the "Actions" column. You may also visit the DMF 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.

OIRA posts its decisions on ICRs online at <http://www.reginfo.gov/public/do/PRAMain> after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Numbers: 1625-0036.

Privacy Act

Anyone can search the electronic form of comments received in 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 a Privacy Act statement regarding Coast Guard public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (79 FR 19105, April 7, 2014) required by 44 U.S.C. 3506(c)(2). We received several comments from one commenter to the 60-day notice. The comments were not related to the periodic renewal of this information collection. The comments were about a mystery oil spill off the Asbury Park coast several years ago.

Information Collection Request

1. *Title:* Plan Approval and Records for U.S. and Foreign Tank Vessels Carrying Oil in Bulk.

OMB Control Number: 1625-0036.

Type of Request: Revision of a currently approved collection.

Respondents: Owners and operators of vessels.

Abstract: This information collection aids the Coast Guard in determining if a vessel complies with certain safety and environmental protection standards. Plans/records for construction or modification of U.S. or foreign vessels submitted and/or maintained on board are needed for compliance with these standards.

Forms: None.

Burden Estimate: The estimated burden has increased from 1,357 hours to 2,032 hours a year due to an increase in the estimated number of respondents.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: July 28, 2014.

Marshall B. Lytle,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Command, Control, Communications, Computers and Information Technology.

[FR Doc. 2014-18604 Filed 8-5-14; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0022]

Agency Information Collection Activities: Request To Enforce Affidavit of Financial Support and Intent To Petition for Custody for Public Law 97-359 Amerasian, Form I-363; Extension, Without Change, of a Currently Approved Collection

ACTION: 60-Day Notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (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 October 6, 2014.

ADDRESSES: All submissions received must include the OMB Control Number 1615-0022 in the subject box, the agency name and Docket ID USCIS-2008-0013. 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 www.regulations.gov under e-Docket ID number USCIS-2008-0013;

(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.

SUPPLEMENTARY INFORMATION:

Comments

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>.

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check "My Case Status" online at: <https://egov.uscis.gov/cris/Dashboard.do>, or call the USCIS National Customer Service Center at 1-800-375-5283.

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:* Request to Enforce Affidavit of Financial Support and Intent to Petition for Custody for Public Law 97-359 Amerasian.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I-363; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households.

(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 I-363 is 50 and the estimated hour burden per response is .5 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 25 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 \$6,125.

If you need a copy of the information collection instrument with instructions, or additional information, please visit the Federal eRulemaking Portal site at: <http://www.regulations.gov>. We may also be contacted at: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, 20 Massachusetts Avenue NW, Washington, DC 20529-2140, Telephone number 202-272-8377.

Dated: July 31, 2014.

Samantha Deshommes,

Supervisory Economist, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2014-18544 Filed 8-5-14; 8:45 am]

BILLING CODE 9111-97-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0090]

Agency Information Collection Activities: Application for Status as Temporary Resident Under Section 245A of the INA, Form I-687; Form I-687WS; Extension, Without Change, of a Currently Approved Collection

ACTION: 60-Day Notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (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 October 6, 2014.

ADDRESSES: All submissions received must include the OMB Control Number 1615-0090 in the subject box, the agency name and Docket ID USCIS-2005-0029. 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 www.regulations.gov under e-Docket ID number USCIS-2005-0029;

(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.

SUPPLEMENTARY INFORMATION:

Comments

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>.

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check "My Case Status" online at: <https://egov.uscis.gov/cris/Dashboard.do>, or call the USCIS National Customer Service Center at 1-800-375-5283.

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:* Application for Status as Temporary Resident under Section 245A of the INA.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I-687; I-687WS; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. The information collection on Form I-687 is required to verify the applicant's eligibility for temporary status, and if the applicant is deemed eligible, to grant the benefit sought.

(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 I-687 and I-687WS combined is 30 and the estimated hour burden per response is 1.167 hours. For the biometric collection that is a part of this information collection, the estimated total number of respondents is 30 and the estimated hour per response is 1.167 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 70 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 \$14,700.

If you need a copy of the information collection instrument with instructions, or additional information, please visit the Federal eRulemaking Portal site at: <http://www.regulations.gov>. We may also be contacted at: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, 20 Massachusetts Avenue NW.,

Washington, DC 20529-2140,
Telephone number 202-272-8377.

Dated: July 31, 2014.

Laura Dawkins,

*Chief, Regulatory Coordination Division,
Office of Policy and Strategy, U.S. Citizenship
and Immigration Services, Department of
Homeland Security.*

[FR Doc. 2014-18542 Filed 8-5-14; 8:45 am]

BILLING CODE 9111-97-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0060]

Agency Information Collection Activities: Medical Certification for Disability Exceptions, Form N-648; Extension, Without Change, of a Currently Approved Collection

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 May 12, 2014, at 79 FR 26979, allowing for a 60-day public comment period. USCIS did receive one comment 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 September 5, 2014. 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. All submissions received must include the agency name and the OMB Control Number [1615-0060].

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>.

SUPPLEMENTARY INFORMATION:

Comments

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check "My Case Status" online at: <https://egov.uscis.gov/cris/Dashboard.do>, or call the USCIS National Customer Service Center at 1-800-375-5283.

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:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Medical Certification for Disability Exceptions.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* N-648; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. USCIS uses Form N-648 to substantiate an applicant's claim for an exception to the requirements of section 312(a) of the Immigration and Nationality Act.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 17,302 with an estimated burden per response of 2 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 34,604.

If you need a copy of the information collection instrument with

supplementary documents, or need additional information, please visit <http://www.regulations.gov>. We may also be contacted at: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529-2134; Telephone 202-272-8377.

Dated: July 31, 2014.

Laura Dawkins,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2014-18540 Filed 8-5-14; 8:45 am]

BILLING CODE 9111-97-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0100]

Agency Information Collection Activities: Request for the Return of Original Documents, Form G-884; Extension, Without Change, of a Currently Approved Collection

ACTION: 60-Day Notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (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 October 6, 2014.

ADDRESSES: All submissions received must include the OMB Control Number 1615-0100 in the subject box, the agency name and Docket ID USCIS-2008-0010. 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 www.regulations.gov under e-Docket ID number USCIS-2008-0010;

(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.

SUPPLEMENTARY INFORMATION:

Comments

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>.

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check "My Case Status" online at: <https://egov.uscis.gov/cris/Dashboard.do>, or call the USCIS National Customer Service Center at 1-800-375-5283.

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:* Request for the Return of Original Documents.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* G-884; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. The information will be used by USCIS to determine whether a person is eligible to obtain original documents(s) contained in an alien file.

(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 G-884 is 7,500 and the estimated hour burden per response is .5 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 3,750 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 \$3,750.

If you need a copy of the information collection instrument with instructions, or additional information, please visit the Federal eRulemaking Portal site at: <http://www.regulations.gov>. We may also be contacted at: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529-2140, Telephone number 202-272-8377.

Dated: July 31, 2014.

Laura Dawkins,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2014-18541 Filed 8-5-14; 8:45 am]

BILLING CODE 9111-97-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0057]

Agency Information Collection Activities: Application of Certificate of Citizenship, Form N-600; Extension, Without Change, of a Currently Approved Collection

ACTION: 60-Day Notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (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 October 6, 2014.

ADDRESSES: All submissions received must include the OMB Control Number 1615-0057 in the subject box, the agency name and Docket ID USCIS-2006-0023. 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 www.regulations.gov under e-Docket ID number USCIS-2006-0023;

(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.

SUPPLEMENTARY INFORMATION:

Comments

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>.

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check "My Case Status" online at: <https://egov.uscis.gov/cris/Dashboard.do>, or call the USCIS National Customer Service Center at 1-800-375-5283.

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:* Application for Certificate of Citizenship.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* N-600; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* *Primary:* Individuals or households. USCIS uses the information on Form N-600 to make a determination that the citizenship eligibility requirements and conditions are met by the applicant so that a certificate of citizenship can be generated.

(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-600 is 57,000 and the estimated hour burden per response is 1.6 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 91,200 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 \$6,982,500.

If you need a copy of the information collection instrument with instructions, or additional information, please visit the Federal eRulemaking Portal site at: <http://www.regulations.gov>. We may also be contacted at: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529-2140, Telephone number 202-272-8377.

Dated: July 31, 2014.

Samantha Deshommes,

Supervisory Economist, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2014-18543 Filed 8-5-14; 8:45 am]

BILLING CODE 9111-97-P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

[Docket ID: BSEE-2014-0006; 14XE8370SD ED10S0000.JAE000 EEGG000000]

Notice of Availability for GENWEST EDRC Study and the National Academy of Sciences Letter Report (on the GENWEST Study); Comment Request

ACTION: Notice.

SUMMARY: The Bureau of Safety and Environmental Enforcement (BSEE) is inviting you to provide comments on the GENWEST Systems, Inc., Effective Daily Recovery Capacity (EDRC) Study, National Academy of Sciences (NAS) Letter Report summarizing its peer review of the GENWEST Study, and comments provided by BSEE regarding each document.

Background: EDRC is a calculation method established within BSEE's and the United States Coast Guard's (USCG) regulations to assign an oil recovery capability value to oil skimming

equipment. Although the EDRC methodology was finalized in the early 1990's and has been an integral component of industry response planning and readiness for the past 20 years, the methodology came under heavy scrutiny in the wake of the 2010 Deepwater Horizon oil spill. This spurred an open debate and ongoing dialogue on how to best improve the EDRC planning standard. In late 2011, BSEE contracted with GENWEST Systems Inc. to evaluate the EDRC methodology and to develop recommendations for improving the planning standard for the mechanical recovery of oil on water. GENWEST's final report produced the concept of Estimated Recovery System Potential (ERSP), an oil encounter rate-based calculator that evaluates mechanical recovery equipment as a complete system as opposed to focusing on an individual component such as a skimmer or an intake pump. Shortly thereafter, BSEE contracted the National Research Council's Ocean Studies Board to conduct an independent, third party peer review of the ERSP methodology. The resulting National Academy of Sciences (NAS) Peer Review Letter Report validated the ERSP standard as a sound methodology and a significant improvement over EDRC. The peer review also identified a number of areas for further consideration where ERSP might be improved. BSEE is continuing to develop and refine the ERSP methodology, with the intent of evaluating ERSP as a potential revision to BSEE's oil spill response plan (OSRP) regulations. This notice provides a high level summary of some of the key elements of both documents, as well as BSEE comments regarding each document. It also includes BSEE's response to recommendations in the NAS Letter Report. While the development of a new planning standard for calculating the mechanical recovery of spills continues to undergo additional research and refinement, this notice provides an early opportunity for public viewing and comment on the GENWEST EDRC Study and NAS Letter Report documents which are available in the regulations.gov docket ID: BSEE-2014-0006 and on the BSEE Web site at <http://www.bsee.gov/Research-and-Training/Oil-Spill-Response-Research/Projects/Project-673/>, as well as an opportunity to comment on the BSEE's responses to the findings and recommendations contained in each document.

DATES: You must submit comments by October 6, 2014. The BSEE may not fully consider comments received after

this date. While BSEE does not intend to publish another notice in the **Federal Register** solely to respond to comments submitted to this specific request, all comments received will be posted in the docket and considered as inputs into the ongoing analyses regarding the effort to improve the existing EDRC planning standard, and will become part of the official agency record for this project. As such, the contents of any comments received may be used and/or cited, as appropriate, in the preambles of future BSEE rulemaking documents that would implement an updated mechanical oil recovery planning standard as part of BSEE's OSRP regulations.

ADDRESSES: You may submit comments and additional materials by any of the following methods.

- Electronically: Go to <http://www.regulations.gov>. In the Search for box, enter BSEE-2014-0006, then click search. Follow the instructions to submit public comments and view supporting and related materials available for this notice.

- Email: oilspillresponsedivision@bsee.gov or mail or hand-carry comments to the Department of the Interior, Bureau of Safety and Environmental Enforcement, Oil Spill Response Division, 381 Elden Street, HE 3327, Herndon, Virginia 20170, Attention: Mr. John Caplis. Please reference *GENWEST EDRC Study and the National Academy of Sciences Letter Report* in your comments and include your name and return address.

FOR FURTHER INFORMATION CONTACT: Mr. John Caplis, Oil Spill Response Division, 703-787-1364, john.caplis@bsee.gov to request additional information about this notice.

SUPPLEMENTARY INFORMATION:

The Current EDRC Planning Standard: The current EDRC planning standard was developed as part of a negotiated rulemaking process involving Federal and state government, industry, and non-governmental organizations following the passage of the Oil Pollution Act (OPA) of 1990 (Pub. L. 10, 1-380, Aug 18, 1990, as amended). This regulatory methodology was intended to quantify the amount of oil spill response equipment (i.e., skimmers) needed by plan holders for an effective response to their worst-case discharge (WCD) spill scenario. The formula for EDRC has not changed since its adoption in 1992:

$$\text{EDRC} = T \times 24 \text{ hours} \times E$$

In this formula, "T" is a skimmer's throughput (or recovery) rate in "barrels per hour" and "E" is an efficiency factor that was set at 20 percent (or 0.2).

In practice, the method has been applied as the hourly throughput rate

(as determined by the manufacturer's assigned nameplate recovery rate) multiplied by 24 hours and then discounted by a 20 percent efficiency factor. The result is an estimate of the number of barrels (bbls) of oil that can be recovered in any daily operational period. If a skimmer requires a pump that determines the throughput of fluids, the pump capacity becomes the determining factor in assigning an EDRC value to a piece of skimming equipment.

The 20 percent efficiency (de-rating) factor was determined through consensus by an Oil Spill Response Plan Negotiated Rulemaking Advisory Committee. The de-rating factor accounts for a mix of environmental and operational considerations (such as temperature, sea state, oil viscosity, hours of daylight, the presence of debris, and the ability to separate oil and water) that would limit or reduce the effectiveness of a skimmer's capability to recover oil over a 24-hour operational period. There are other critical influences on mechanical recovery that were not incorporated into the EDRC calculation. Some of the most important factors omitted include oil encounter rate (i.e., the rate at which a skimmer is able to access spilled oil), onboard storage capacity, and human factors (proficiency in skimmer operation).

Observations and Criticisms of EDRC During the Deepwater Horizon Oil Spill: The Deepwater Horizon oil spill dramatically highlighted how mechanical recovery systems can be significantly limited by low encounter rates. Emanating from a well nearly a mile below the ocean surface, the spilled oil surfaced over a wide geographical area and had already thinned much in terms of oil thickness. The oil slick that was available for recovery was widely discontinuous, had a large, expanding areal footprint, and a rapidly diminishing surface thickness. An unprecedented quantity of skimmers, boom, and other types of spill response equipment were cascaded in from across the United States, as well as from other nations, resulting in a massive amount of offshore mechanical recovery capability that was used during the response. Despite this effort, the aforementioned factors worked against the mechanical recovery task forces operating offshore—reducing their overall effectiveness in encountering, containing and recovering the oil. As a result, significant amounts of shoreline oiling occurred across the Gulf of Mexico. Both government and industry-sponsored lessons learned reports identified the performance and effectiveness of skimming systems as a

focal point in their observations and findings.

The National Commission on the BP Deepwater Horizon Oil Spill and Offshore Drilling's Final Report, BP Deepwater Horizon Incident Specific Preparedness Review (ISPR) Final Report, and Joint Industry Oil Spill Preparedness and Response Task Force (JITF) Second Progress Report all highlight the limitations of the EDRC methodology, and recommend improvement of the mechanical recovery planning standard. The National Commission report states that EDRC should be revised to encourage the development of more efficient systems. The BP Deepwater Horizon ISPR Report points out that the total EDRC for equipment used on-scene during the spill far exceeded BP's mandated OSRP requirements. However, this extensive armada of mechanical recovery equipment did not recover oil quantities that corresponded to their aggregated EDRC values. The ISPR Report recommends that the regulations be revised to include a reliable, dynamic efficiency measure that accurately reflects the limitations of encountering significant volumes of oil on the water, and also should encourage more research and development to improve the effectiveness of skimmer systems. The JITF Second Progress Report states that government and industry must recognize the limitations of existing mechanical recovery equipment, and pursue incentives to improve boom and skimmer designs, especially in the offshore environment. Furthermore, the JITF also recommends that the government revisit the EDRC regulations in order to determine if improvements to the planning standard are necessary.

The EDRC Study: Through a competitive procurement, BSEE initiated a third party, independent research contract to:

- (1) Evaluate existing EDRC methodologies,
- (2) examine de-rating in order to identify the key variables that impact skimming system recovery rates,
- (3) develop recommendations for an improved mechanical recovery planning standard, and
- (4) create a user-friendly, computer-based planning tool based on those recommendations.

GENWEST Systems, Inc., a private sector information management and environmental services consulting firm, was awarded the research contract in September 2011 and completed its final project report in December 2012.

The capstone of the GENWEST report is a new methodology and computer-

based planning tool for estimating mechanical oil recovery capability called the ERSP calculator. Based on algorithms similar to those within the GENWEST developed Response Options Calculator, the ERSP calculator is an oil encounter-rate based planning tool that measures the performance of an entire mechanical recovery skimming system.

The ERSP calculator addresses the effect of encounter rate on a skimmer through three key variables: The swath width of the skimming system configuration, the speed of advance of the skimming system relative to the motion of the oil slick, and the thickness of the oil being collected. The calculator uses three different nominal oil thicknesses that decrease with time over a 3-day period in order to model the reduced amounts of oil available to a skimming system due to the effects of spreading. The selection of the nominal oil thickness values (0.1 inch for Day 1, 0.05 inch for Day 2, and 0.025 inch for Day 3) are based on the results of over 400 computer simulations of oil spreading where temperature, wind, discharge volume, and oil type were varied in different combinations. The three resulting thicknesses that were selected are representational values that are reasonably acceptable across a wide range of scenarios. The calculator enables the plan holder to input customized values for both the swath width and the speed of advance for a skimming system, which are then used to estimate areal coverage for a recovery system during an operational period. The calculator then applies the nominal oil thicknesses to the areal coverage achieved in order to estimate the oil encountered.

The next steps in the ERSP methodology apply the "recovery" parameters of the skimming system to the amount of the oil encountered. These parameters include an estimate of the oil recovered compared to the total volume of the fluids recovered (i.e., the oil/water recovery ratio otherwise referred to as the system's Recovery Efficiency), an estimate of the oil removed compared to the oil encountered (i.e., the effectiveness of the containment elements of the skimming system as opposed to entrainment of the oil, referred to as Throughput Efficiency), the skimmer nameplate recovery rate, the amount of onboard fluid storage, decanting or oil/water separation abilities, intake and offload pump rates, and offloading set up and transit times. The application of the "encounter rate" and "recovery" system variables, when applied to the available oil thicknesses for each operational period, create estimates of

the system's effective recovery potentials for Day 1, Day 2, and Day 3 of a spill. If a skimming system's configuration remains fixed over time, then the recovery potential of the system will decrease from day to day as the oil available for skimming also decreases; however, a skimming system's configuration can often be adjusted during subsequent operational periods to maintain or minimize the loss of recovery potential.

The National Academy of Sciences Letter Report: The National Academy of Sciences (NAS) is a nonprofit, self-perpetuating society of scholars dedicated to the furtherance and use of science and technology for the general welfare. Under the charter granted to it by Congress, the Academy has a mandate to advise the Federal government on scientific and technical matters. The National Research Council was organized by the NAS as the principal operating agency for the Academies in providing services to government, the public, and the scientific communities. In the spring of 2013, BSEE contracted the National Research Council's Ocean Studies Board to conduct an objective technical evaluation of the GENWEST EDRC Report and the ERSP methodology. The Ocean Studies Board assembled an ad hoc study committee of five subject matter experts that completed and delivered their Peer Review Letter Report in November of 2013.

The Letter Report concluded that the ERSP methodology was sound and a substantial improvement over the current EDRC methodology. While the committee cited many improvements, they felt that the greatest strength of the new ERSP methodology was its evaluation of the entire skimming system as a whole as opposed to any single part of it.

The committee's most significant concerns regarding the ERSP's methodology focused on the nominal oil thicknesses selected by the GENWEST team. These thicknesses were meant to be representative of the "thickest" oil available during each operational period. The ERSP methodology assumes that a skimming system will be able to operate in oil at these nominal thickness values for the entire time it is skimming during the operational periods on the first three days. The committee, however, felt that the real distribution of thick oil will be discontinuous, or patchy, and that the ERSP model should address this factor in its calculations. The Letter Report also goes on to suggest that some field observations for slick thicknesses are generally less than those used by the ERSP calculator. The study

committee concluded that the GENWEST thicknesses are likely to overestimate actual encounter rates and would provide an overly optimistic assessment of a skimming system's actual recovery potential. The committee recommended applying a "patchiness de-rating factor" to the encounter rate calculation, and also suggested adding the ability to enter different oil thickness values into the calculator. Encounter rates would then be adjusted for the discontinuous nature of the thick oil patches, and more customized thicknesses could be entered into the calculator based on the circumstances of the release scenario and the particular properties of the plan holder's oil type.

The committee also recommended that regulators work with the GENWEST team to develop a more detailed user manual that would further explain the ERSF calculator assumptions, provide additional guidance to users on the selection of certain input values, and would provide default values for some of the more uncertain or unknown parameters. The committee also recommended the use of the American Society for Testing and Materials (ASTM) Standard F2709-08, as the means to determine the Nameplate Recovery Rate value in the ERSF calculator. Finally, the committee recommended a broader approach of considering all potential response options in future rulemakings.

BSEE Comments Regarding the GENWEST Study: BSEE believes the GENWEST EDRF study provides a solid foundational work for building an improved mechanical recovery planning standard. The ERSF methodology has necessarily sacrificed the increased accuracy of a more complex and customizable model in order to create a simple, accessible planning tool that is applicable across a wide range of planning scenarios. In striking this important balance, the ERSF methodology successfully addresses many of the issues identified concerning EDRF, and also incorporates some key compromises into its assumptions and algorithms that BSEE will have to examine carefully. BSEE submits the following statements for public review and comment regarding its assessment of the ERSF calculator and the GENWEST EDRF Study:

ERSF Creates Incentives for More Effective Skimming Systems: The ERSF methodology is a practical approach to evaluating mechanical oil recovery systems that includes incentives for improving system performance. The ERSF calculator rewards recovery systems that maximize encounter rate

and minimize skimming downtime during offloading periods. The calculator provides plan holders and Oil Spill Removal Organizations (OSROs) with a very useful tool for assessing and comparing different configurations for almost any type of skimming system. Plan holders can input different values into the calculator for many of the recovery system's variables, such as swath width, speed, decanting, onboard storage, and pump rates, in order to explore the resultant effects on encounter rate and recovery potential. Plan holders and OSROs will be able to identify the parameters that will best increase a system's recovery potential, and should be able to use this information to guide their design, investment, and operational deployment decisions.

The calculator's algorithms will encourage plan holders and OSROs to acquire and configure skimming systems with higher areal coverage rates (through increased swath widths or increased speeds of advance relative to the motion of the oil), higher nameplate capacities and recovery efficiencies, and more effective collection and containment arrangements that limit the entrainment of oil. The calculator will also create incentives for developing skimming systems that have increased onboard storage, faster oil transfer rates, and effective decanting capabilities.

ERSF Challenges in the Nearshore and Inshore Operating Environments: ERSF algorithms and operating incentives are well suited for offshore skimming operations, but are less so for the nearshore and inland operating environments. Decanting in the offshore environment provides a tremendous advantage that maximizes the use of onboard storage and reduces offload times. However, decanting is not realistic for many nearshore and inshore scenarios. In more confined, shallow areas, skimming systems with large swath widths and large onboard or tethered storage solutions are likely to be ineffective. Advancing skimmers used in nearshore areas will still require high recovery efficiencies; however, shallow drafts and maneuverability now become more important than large swath widths and bulky onboard storage arrangements. As a result, many nearshore skimming systems are likely to have ERSF potential values significantly below their EDRF ratings, despite being optimally configured for their operating environments. Mechanical recovery in inshore areas is even more disassociated with many of the incentives of the ERSF calculator, as mechanical recovery in these settings often relies on deflection and collection

booming and stationary skimming arrangements.

While ERSF may still be a useful measure of potential in the nearshore area, limits may be necessary on the use of certain ERSF variables, such as swath width and decanting. It may also be necessary to consider a mixture of different equipment rating schemes and requirements for mechanical recovery in these operating environments. The rating of skimming systems and the reviews of OSROs in these operating areas may require a more scenario-based approach than regulators have used in the past.

ERSF Emphasizes a Rapid Response Capability: As the calculator applies substantially decreasing oil thicknesses over the first 3 days of a spill, the ERSF methodology creates a powerful incentive for skimming systems to arrive onsite as quickly as possible. The calculator clearly demonstrates that plan holders and responders will reach a point of diminishing returns for bringing in additional mechanical recovery equipment as time progresses and oil becomes less available for skimming. While this circumstance is somewhat mitigated during a sustained release such as a well blowout (where there may be fresh, thick, concentrated oil available each day), the fact remains that mechanical recovery equipment performs at its highest recovery potential in the earliest hours of a spill when encounter rates can be maximized.

ERSF Does not Address Staging, Mobilization, or Transit Times: While the ERSF methodology emphasizes a rapid response, it does not factor into its calculations the time it takes to mobilize and deliver a mechanical recovery system to the site of a spill. GENWEST, at the direction of BSEE, used a fixed operational period of 12 hours for the EDRF Study, and did not incorporate the effects of equipment mobilization and delivery times on recovery potentials. The ERSF calculator does, however, have an input variable for each day's "operating period", which could be reduced to account for these factors related to response time.

The OSROs and plan holders could adjust the operating period accordingly if BSEE provides guidance on how to account for each mobilization factor. The BSEE currently does not factor response times into its regulations and currently does not require adjustments to EDRF values based on mobilization times. Additional guidance and regulations may be needed in order to adequately account for mobilization times when inputting the operational period into the ERSF calculator.

ERSP Calculations Assumes the Use of Best Practices and Best Commercially Available Technology: In the selection of representative oil thicknesses for each operational period, the ERSP calculator assumes that operators will be using the best technologies commercially available, such as remote sensing tools, as well as operational best practices, in their skimming activities. This is especially important for ensuring operator proficiency, and for identifying, tracking, and keeping recovery systems in thick oil continuously during skimming operations. If operators do not employ such technology and best practices, then the ERSP calculator is likely to provide an overstated recovery potential for a system. The calculator does not include any built in incentives for the use of these critical best practices and technologies. Creating these incentives or requirements may therefore have to be addressed through regulatory requirements, industry standards, and recommended practices.

BSEE Comments Regarding the NAS Letter Report: The BSEE agrees with the NAS Letter Report findings that the new approach for evaluating mechanical recovery equipment, Estimated Recovery System Potential (ERSP), is basically sound and an improvement over methods currently employed by BSEE and USCG oil spill response planning regulations. The BSEE also acknowledges each of the insightful recommendations offered for possible improvement in the NAS Peer Review Letter Report, and has carefully considered their potential for improving the existing EDRC and proposed ERSP methodologies. As stated earlier in this document, BSEE believes that the ERSP methodology has necessarily sacrificed a degree of accuracy associated with a more complex and customizable model in order to create a simple, accessible planning tool that is applicable across a wide range of planning scenarios. In striking this important balance, the ERSP methodology successfully addresses many of the issues concerning EDRC, but also incorporates some key compromises into its assumptions and algorithms. The NAS Letter Report identifies some of these compromises as shortfalls, and provides several recommendations that would increase the accuracy of the ERSP calculator, but would also significantly increase the complexity of using the calculator. BSEE carefully weighed these sometimes opposing factors when evaluating the NAS recommendations, and ultimately placed a premium on ensuring the calculator remained a

simple, useful planning tool that is best suited to the needs of plan holders and government reviewers. Where BSEE could not fully address the NAS's concerns or suggested improvements with changes to the ERSP calculator itself, BSEE will work to address the issues where possible through other associated processes such as potential changes to the OSRP regulations. As such, BSEE provides the following comments with regard to the NAS recommendations:

Using a "System of Response Options" Approach: The NAS recommends BSEE consider adopting a systems approach in the OSRP regulations that incorporates other response options in addition to mechanical oil recovery capabilities. BSEE fully agrees with this statement and will be conducting further studies to explore the development of additional planning tools and potential requirements for other response options such as dispersants and in situ burning.

Using an ASTM Standard to Estimate Nameplate Recovery Rate and Recovery Efficiency of a Skimming System: The NAS recommends that the nameplate recovery rate input parameter for a skimmer be generated through the use of operational testing using a standard such as ASTM F2709–08. The NAS also recommends that the input value for skimmer Recovery Efficiency (RE) could be generated by using ASTM F2709–08 or a similar standard. While BSEE would agree with the suggestion to use ASTM standards whenever appropriate, it should be noted that the ASTM F2709–08 standard tests a skimming system's performance in ideal conditions to determine a skimmer's nameplate recovery rate, and does not account for the effects of sea state or other operating conditions that may reduce a system's effectiveness and efficiency. ASTM F2709–08 does offer the promise as a low cost, easily replicated test for producing Nameplate Recovery Rate input values. As this testing method provides an assessment of optimal recovery rates measured under ideal skimming conditions, BSEE has been in discussions with members of the ASTM F20 Committee on how to best apply the existing standard or with regard to possible adjustments to the F2709–08. BSEE will continue to discuss and evaluate the practicality of using ASTM 2709–08, or of developing a new or revised standard that would complement the use of ERSP with ASTM.

Developing More Guidance on Selecting Input Values and a More Detailed ERSP User Manual: The NAS recommends developing a more detailed

user manual that provides the logic behind the default values for certain parameters, and provides additional guidance for selecting and entering each of the user-defined inputs. BSEE agrees that additional information in a more detailed user manual would be beneficial to both response plan holders and government reviewers. BSEE will implement this recommendation to provide more background information on ERSP assumptions and any specified default values, and develop additional guidance on the selection of user-defined input variables in a more detailed user manual.

Reducing Oil Thickness Values to Account for the Discontinuous Nature of Oil Slicks: The NAS recommended adjustment of the ERSP methodology to account for the discontinuous nature of oil slicks, specifically as it relates to a skimming system's ability to continuously encounter oil for removal. Additionally, NAS reviewers observed that the representative oil thickness values chosen by GENWEST are higher than those gathered during field observations from actual spills or laboratory tests. The NAS concluded that the lack of a spatial element for the patchiness of oil slicks along with the current values chosen for oil thicknesses in the ERSP calculator would overstate oil encounter rates and recovery potential values, especially on Day 2 and Day 3 of a spill. The BSEE acknowledges the discontinuous nature of most oil spills as well as the fact that choosing a set of oil thickness values that adequately represent actual encounter rates over a wide range of scenarios is a very important but extremely challenging aspect of developing the ERSP calculator. The BSEE discussed this process at length with the GENWEST study team, and believes the values selected for oil thicknesses by the GENWEST team are valid planning values that adequately cover the very wide range of variables involved across a very broad set of industry response plans, and do not need to be further adjusted. The GENWEST study team ran over 400 modeling simulations varying for oil type, spill size, and ambient conditions such as wind and temperature in order to generate the distribution of expected thickness values. GENWEST informed BSEE that they factored in the discontinuous nature of oil slicks in their modeling when they selected the thickness values. GENWEST also commented that the thickness values were selected with a bias toward responding to a very large worst case discharge (WCD) spill volume, which

would increase the thickness values over those measured during smaller controlled discharges and spills of opportunity. BSEE agrees with these statements and believes the thickness values selected by GENWEST are valid for addressing response planning to a WCD as required under the OPA.

Incorporating Multiple Oil Thickness Scenarios Into the ERSP Calculator: The NAS recommends developing several planning scenario options that would allow plan holders to fine tune and customize their oil thickness values based on their oil type and facility-specific parameters. This would allow a plan holder to tailor their ERSP calculations for their specific operational conditions (such as a sustained subsea loss of well control of medium crude oil in the Gulf of Mexico or a well with heavy crude in the Arctic). While these recommendations may improve the accuracy of individual plan holders' specific ERSP calculations, BSEE believes the significant increase in complexity associated with using this approach far outweighs the minimal gains in accuracy that might be realized for an individual plan holder's ERSP values. At this time, BSEE does not plan to incorporate multiple scenarios that would require the customized inputs for oil thickness values to be estimated or selected based upon a plan holder's oil type, environmental operating conditions, and discharge scenarios.

Assigning Uncertainty Values to ERSP Input Values: The NAS suggests adding the ability for users to input uncertainty values attached to user-selected inputs, and that additional guidance in the user manual should be developed to guide users on how to interpret and use the outputs that would result. The end result of using these uncertainty values would be to create a probability range of ERSP outcomes rather than a singularly defined number, which the NAS believed would provide additional clarity on the accuracy of the ERSP data generated. BSEE does not believe it is necessary for users to develop and input uncertainty data, as this may unnecessarily complicate the use of the calculator tool, and would not result in additional information that is necessary for developing and/or reviewing effective OSRPs.

Additional Public Review: The NAS recommended the calculator methodology be exposed to an additional round of public review by a broad range of subject matter experts. Currently, BSEE relies on the NAS Letter Report itself as the primary means for subjecting the ERSP study to a rigorous "expert" assessment. However,

BSEE fully acknowledges the value of additional public review of critical documents such as the EDRC Study. BSEE believes publishing this **Federal Register** notice that announces the results of both the EDRC Study and NAS Letter Report (as well as BSEE's analysis and response to these documents), and providing an opportunity for public review and comment, successfully meets the intent of the NAS recommendation. Additionally, if any portion of the ERSP methodology were to be incorporated into a future Notice of Proposed Rulemaking (NPRM), there would be another opportunity, in addition to this **Federal Register** notice, for public review and comment.

Public Availability of Comments: 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.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although all documents submitted will be listed in the index, some information may not be publicly available, e.g., confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, may be publicly available only in hard copy. Otherwise, publicly available docket materials are available electronically in <http://www.regulations.gov>.

Dated: July 29, 2014.

David M. Moore,

Chief, Oil Spill Response Division.

[FR Doc. 2014-18608 Filed 8-5-14; 8:45 am]

BILLING CODE 4310-VH-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R4-ES-2014-N166; 41910-1112-0000-F2]

Endangered and Threatened Wildlife and Plants; Receipt of Application for Incidental Take Permit; Availability of Proposed Low-Effect Habitat Conservation Plan; City of Deltona, Volusia County, FL and Adventist Health System/Sunbelt, Inc., Orange County, FL

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt; request for comment/information.

SUMMARY: We, the Fish and Wildlife Service (Service), have received applications from the City of Deltona and Adventist Health System/Sunbelt, Inc. (applicants) for incidental take permits under the Endangered Species Act of 1973, as amended (Act). The City of Deltona has applied for modification of an ITP (ITP; modification #TE28377B-1), and Adventist Health System/Sunbelt, Inc. has applied for a 10-year incidental take permit (ITP; #TE41877B-0).

We request public comment on the permit applications and accompanying proposed habitat conservation plans (HCPs), as well as on our preliminary determination that the plan qualifies as low-effect under the National Environmental Policy Act (NEPA). To make this determination, we used our environmental action statement and low-effect screening form, which are also available for review.

DATES: To ensure consideration, please send your written comments by September 5, 2014.

ADDRESSES: If you wish to review the applications and HCPs, you may request documents by email, U.S. mail, or phone (see below). These documents are also available for public inspection by appointment during normal business hours at the office below. Send your comments or requests by any one of the following methods.

Email: northflorida@fws.gov. Use "Attn: Permit number TE28377B-1" as your message subject line for the City of Deltona and "Attn: Permit number TE41877B-0" for Adventist Health System/Sunbelt, Inc.

Fax: Field Supervisor, (904) 731-3045, Attn.: Permit number TE28377B-0 or TE41877B-0.

U.S. mail: Field Supervisor, Jacksonville Ecological Services Field Office, Attn: Permit number TE28377B-0 or TE41877B-0, U.S. Fish and

Wildlife Service, 7915 Baymeadows Way, Suite 200, Jacksonville, FL 32256.

In-person drop-off: You may drop off information during regular business hours at the above office address.

FOR FURTHER INFORMATION CONTACT: Erin M. Gawera, telephone: (904) 731-3121; email: erin_gawera@fws.gov.

SUPPLEMENTARY INFORMATION:

Background

Section 9 of the Act (16 U.S.C. 1531 *et seq.*) and our implementing Federal regulations in the Code of Federal Regulations (CFR) at 50 CFR part 17 prohibit the “take” of fish or wildlife species listed as endangered or threatened. Take of listed fish or wildlife is defined under the Act as “to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct” (16 U.S.C. 1532). However, under limited circumstances, we issue permits to authorize incidental take—i.e., take that is incidental to, and not the purpose of, the carrying out of an otherwise lawful activity.

Regulations governing incidental take permits for threatened and endangered species are at 50 CFR 17.32 and 17.22, respectively. The Act’s take prohibitions do not apply to federally listed plants on private lands unless such take would violate State law. In addition to meeting other criteria, an incidental take permit’s proposed actions must not jeopardize the existence of federally listed fish, wildlife, or plants.

Applicant’s Proposal

The City of Deltona is requesting additional take of approximately 0.9 acres (ac) of occupied Florida scrub-jay foraging and sheltering habitat incidental to construction of a 24-ac public park. The existing 10-year permit is for take of approximately 1.9 acres (ac) for a 35-ac public utility on the same property. The 122-ac project site is located on parcel numbers

31183166150001, 31183105150010, 31183105140010, 31183105130010, 31183105120010, 31183105110010, 31183105160010, 31183105170010, 31183105180010, 31183105190010, 31183105200010, 31183104050010, 31183104040010, 31183104030010, 31183104020010, 31183104010010, 31183166170001, 31183104060010, 31183104070010, 31183104080010, 31183104090010, 31183104100010, 31183103010010, 31183103020010, 31183103030010, 31183103040010, 31183103050010, 31183103060010, 31183103070010, 31183103080010, 31183103090010, 31183103100010, 31183103030010, and 31183103080160,

within Section 31, Township 18 South, Range 31 East, Volusia County, Florida. The project includes construction of a public park and public utility and the associated infrastructure, and landscaping. The applicant proposes to mitigate for the take of the Florida scrub-jay through the additional deposit of good funds in the amount of \$13,320.90 to the Nature Conservancy’s Conservation Fund, for the management and conservation of the Florida scrub-jay based on Service Mitigation Guidelines. The applicant has deposited \$56,243.80 to the Nature Conservancy’s Conservation Fund for the public utilities.

Adventist Health System/Sunbelt, Inc. is requesting take of approximately 3.08 acres (ac) of occupied sand skink foraging and sheltering habitat incidental to construction of a 73-ac hospital, and seeks a 10-year permit. The 73-ac project site is located on parcel numbers 20-21-28-0000-00-007, 20-21-28-0000-00-042, 20-21-28-0000-00-044, and 20-21-28-0000-00-046, within Section 20, Township 21 South, Range 28 East, Orange County, Florida. The project includes construction of a hospital and the associated infrastructure, and landscaping. The applicant proposes to mitigate for the take of the sand skink by the purchase of 6.2 mitigation credits within the Sebring Scrub Conservation Bank.

Our Preliminary Determination

We have determined that the applicant’s proposals, including the proposed mitigation and minimization measures, would have minor or negligible effects on the species covered in the HCPs. Therefore, we determined that the ITPs are “low-effect” projects and qualify for categorical exclusions under the National Environmental Policy Act (NEPA), as provided by the Department of the Interior Manual (516 DM 2 Appendix 1 and 516 DM 6 Appendix 1). A low-effect HCP is one involving (1) Minor or negligible effects on federally listed or candidate species and their habitats, and (2) minor or negligible effects on other environmental values or resources.

Next Steps

We will evaluate the plans and comments we receive to determine whether the ITP applications meets the requirements of section 10(a) of the Act (16 U.S.C. 1531 *et seq.*). If we determine that the applications meet these requirements, we will issue ITP #TE28377B-1 and TE41877B-0. We will also evaluate whether issuance of the section 10(a)(1)(B) ITPs comply with

section 7 of the Act by conducting intra-Service section 7 consultations. We will use the results of these consultations, in combination with the above findings, in our final analysis to determine whether or not to issue the ITPs. If the requirements are met, we will issue the permits to the applicants.

Public Comments

If you wish to comment on the permit application, plan, and associated documents, you may submit comments by any one of the methods in

ADDRESSES.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comments, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

We provide this notice under Section 10 of the Act and NEPA regulations (40 CFR 1506.6).

Dated: July 28, 2014.

Jay B. Herrington,
Field Supervisor, Jacksonville Field Office.

[FR Doc. 2014-18591 Filed 8-5-14; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R5-ES-2014-0020; 50120-1112-0000]

Availability of a Revised Environmental Assessment and Incidental Take Plan for the Maine Department of Inland Fisheries and Wildlife’s Trapping Program

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: On November 9, 2011, we, the U.S. Fish and Wildlife Service (Service), published a notice of availability of a draft environmental assessment (DEA) and receipt of an application for an incidental take permit (permit) pursuant to the Endangered Species Act of 1973, as amended (ESA), submitted by the Maine Department of Inland Fisheries and Wildlife (MDIFW), for the Maine Trapping Program Incidental Take Plan (ITP). MDIFW is requesting a permit

under the ESA to authorize take of the federally threatened Canada lynx incidental to otherwise lawful activities associated with MDIFW's statewide furbearer trapping program. The permit would be in effect for 15 years.

During the 60-day comment period, the Service received numerous comments on the DEA and the ITP. MDIFW revised the draft ITP to address public and Service comments and submitted a revised ITP to the Service in July 2013. The Service then revised its DEA. This notice announces the availability for a 30-day supplemental public comment period of both the revised DEA and the revised ITP for MDIFW's incidental take permit application.

DATES: To ensure consideration, we must receive your written comments by September 5, 2014. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** section, below) must be received by 11:59 p.m. Eastern Time on the closing date.

ADDRESSES: Written comments may be submitted electronically via the Federal eRulemaking Portal: <http://www.regulations.gov>, or in hard copy, via U.S. mail, to: Public Comments Processing, Attn: FWS-R5-ES-2014-0020; U.S. Fish and Wildlife Service Headquarters, MS: BPHC; 5275 Leesburg Pike; Falls Church, VA 22041-3803.

FOR FURTHER INFORMATION CONTACT: Laury Zicari, by U.S. mail at the U.S. Fish and Wildlife Service, Maine Field Office, 17 Godfrey Drive, Suite #2, Orono, ME 04473; or by phone at 207-866-3344.

SUPPLEMENTARY INFORMATION:

Background

On November 9, 2011 (76 FR 69758), the Service published a notice of availability of a draft environmental assessment (DEA) and receipt of an application for an incidental take permit (permit), pursuant to section 10(a)(1)(B) of the ESA (16 U.S.C. 1531 *et seq.*), for the Maine Trapping Program Incidental Take Plan (ITP). The Maine Department of Inland Fisheries and Wildlife (MDIFW) is requesting a permit under the ESA to authorize take of the federally threatened Canada lynx (*Lynx canadensis*) incidental to otherwise lawful activities associated with MDIFW's statewide furbearer trapping programs (i.e., fur trapping, animal damage, and predator management control). The permit would be in effect for 15 years.

During the 60-day comment period, which ran through January 9, 2012, the Service received numerous comments

on the DEA and the draft ITP. The MDIFW revised the draft ITP to address public and Service comments and submitted a revised ITP to the Service on July 29, 2013. The Service then revised its DEA. This notice announces the availability for a 30-day supplemental public comment period of both the revised DEA and the revised ITP for MDIFW's incidental take permit application.

How Incidental Take Permits Work

Section 9 of the ESA (16 U.S.C. 1531 *et seq.*) and its implementing regulations prohibit the "take" of animal species listed as endangered or threatened. Take is defined under the ESA as to "harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect listed animal species, or to attempt to engage in such conduct" (16 U.S.C. 1538). However, under section 10(a)(1)(B) of the ESA, we may issue permits to authorize incidental take of listed species. "Incidental take" is defined by the ESA as take that is incidental to, and not the purpose of, carrying out an otherwise lawful activity. Regulations governing incidental take permits for threatened and endangered species, respectively, are found in the Code of Federal Regulations (50 CFR 17.22 and 17.32).

If an incidental take permit is granted to MDIFW, the State and licensed trappers conducting otherwise legal trapping activities would be authorized to incidentally take Canada lynx according to limitations prescribed in the revised ITP, along with any additional conditions the Service determines are necessary and appropriate for issuance of an incidental take permit.

Applicant's Revised Incidental Take Permit Application

On July 29, 2013, the Service received a revised ITP from MDIFW that incorporates changes responding to comments from the public and the Service. The revised ITP includes important changes and clarifications from MDIFW's previous draft ITP, which was submitted to the Service in 2008 and released for comment in 2011 (76 FR 69758). Under the covered activities of the revised ITP, MDIFW includes predator management and animal damage control programs, in addition to recreational fur trapping. Several new methods of trapping and new trapping regulations would be implemented, including lifting the size restrictions on foothold traps. Measures to avoid and minimize take have been updated to include increased veterinary oversight, protocols for responding to

orphan kittens, increased trapper outreach, and increased compliance monitoring. Further, the revised ITP incorporates additional contingencies to address a number of potential changed circumstances. The requested incidental take over the 15-year duration of the permit is increased to 195 incidentally trapped lynx, of which 9 may experience major injury and 3 may die. The other incidentally trapped lynx would be released with no or minor injuries. Finally, MDIFW has clarified the mitigation strategy and seeks to address the impact of lynx mortalities. Mitigation consists of maintaining and enhancing at least 4,785 acres of lynx habitat on a 10,411-acre area on the Maine Division of Parks and Public Lands Sebomook Unit in northern Maine.

Service's Revised Draft Environmental Assessment

The Service has revised its DEA to reflect MDIFW's revised ITP. The changes to the DEA include: (1) A revised purpose and need for a permit; (2) new alternatives to the proposed action; (3) a description of the aspects of the human environment that would be affected by MDIFW's trapping programs; and (4) an evaluation of the environmental consequences of the proposed project and the mitigation measures.

The DEA considers four alternatives:

(1) Status quo: No action, no incidental take permit is issued, and trapping continues in its current form consistent with the requirements of the 2007 Consent Decree. The Consent Decree is a settlement agreement stemming from an earlier lawsuit, *Animal Protection Institute v. Roland D. Martin*, which imposes a number of restrictions on trapping activities in lynx wildlife management districts. Fur trapping, predator management, and animal damage control continue statewide in this alternative.

(2) No action: No incidental take permit is issued, and, to avoid take of lynx, MDIFW discontinues all trapping programs in lynx wildlife management districts.

(3) Proposed action: An incidental take permit is issued to MDIFW, and measures in the 2013 revised ITP are implemented.

(4) An incidental take permit is issued to MDIFW for statewide fur trapping, but the predator management and animal damage control programs in lynx wildlife management districts are discontinued. Fur trapping measures in the 2013 revised ITP are implemented.

For alternatives 2 to 4, we presume that the described programs would

replace the requirements of the 2007 Consent Decree, which would ultimately be rescinded. A number of issues that were raised during the initial public comment period on the DEA are still relevant to the revised proposed action. Therefore, the Service's DEA also has included a response to comments to explain how those issues are handled in MDIFW's revised ITP and the Service's revised DEA.

Next Steps

We will evaluate the revised ITP and comments we receive on the Service's revised DEA to determine whether the permit application meets the requirements of section 10(a) of the ESA (16 U.S.C. 1531 *et seq.*). We will also evaluate whether issuance of a section 10(a)(1)(B) permit would comply with section 7 of the ESA by conducting an intra-Service section 7 consultation. We will use the results of this consultation, in combination with the above findings, in our final analysis to determine whether to issue a permit. If the requirements are met, we will issue the permit to the applicant.

Authority

This notice is provided pursuant to section 10(c) of the ESA and the National Environmental Policy Act regulations (40 CFR 1506.6).

Dated: July 22, 2014.

Paul R. Phifer,

Assistant Regional Director, Ecological Services.

[FR Doc. 2014-18548 Filed 8-5-14; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R3-ES-2014-N159;
FXES11130300000-145-FF03E00000]

Endangered and Threatened Wildlife and Plants; Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (USFWS), invite the public to comment on the following applications we've received for permits to authorize take of federally listed species. Although the Endangered Species Act (Act) prohibits the take of species listed as endangered or threatened under the Act, the USFWS may issue permits authorizing the take of endangered or threatened species if certain conditions are met by the

applicant, and when such take will not appreciably reduce the likelihood of the survival and recovery of the species in the wild. The Act requires that we invite public comment before we issue these permits.

DATES: We must receive any written comments on or before September 5, 2014.

ADDRESSES: Send written comments by U.S. mail to the Regional Director, Attn: Thomas J. Magnuson, U.S. Fish and Wildlife Service, Ecological Services, 5600 American Blvd. West, Suite 990, Bloomington, MN 55437-1458; or by electronic mail to permitsR3ES@fws.gov.

FOR FURTHER INFORMATION CONTACT: Thomas J. Magnuson, (612) 713-5467.

SUPPLEMENTARY INFORMATION:

Background

We invite public comment on the following permit applications for certain activities with federally listed species authorized by section 10(a)(1)(A) of the Act (16 U.S.C. 1531 *et seq.*) and our regulations governing the taking of endangered species in the Code of Federal Regulations (CFR) at 50 CFR part 17. Submit your comments, or request for a copy of the complete application to the mailing address or email address shown in **ADDRESSES**.

Permit Applications

Permit Application Number: TE40128B

Applicant: Charles Morgan, Mainstream Commercial Divers, Inc.

The applicant requests a permit to take (survey, capture and release; non-destructive sampling) all threatened and endangered unionid mussels within the States of Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Iowa, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Ohio, Pennsylvania, Tennessee, West Virginia, and Wisconsin. Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Permit Application Number: TE82666A

Applicant: Justin Boyles, University of Southern Illinois

The applicant requests a permit amendment to add the northern long-eared bat (*Myotis septentrionalis*) to their permit. The requested amendment would also add personnel to the permit. Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Permit Application Number: TE049738

Applicant: Foree Davis, Third Rock Consultants, LLC.

The applicant requests a permit amendment to add the following mussel and fish species to their permit. Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Mussel Species

Alabama lampmussel (*Lampsilis virescens*)
Alabama moccasinshell mussel (*Medionidus acutissimus*)
Appalachian elktoe mussel (*Alasmidonta raveneliana*)
Appalachian monkeyface mussel (*Quadrula sparsa*)
Birdwing pearlymussel (*Lemiox rimosus*)
Coosa moccasinshell (*Medionidus parvulus*)
Cracking pearlymussel (*Hemistena lata*)
Finelined pocketbook mussel (*Lampsilis altilis*)
Finerayed pigtoe mussel (*Fusconaia cuneolus*)
Fluted kidneyshell mussel (*Ptychobranthus subtentum*)
Georgia pigtoe mussel (*Pleurobema hanleyianum*)
Green blossom pearlymussel (*Epioblasma torulosa gubernaculum*)
Ovate clubshell mussel (*Pleurobema perovatum*)
Pale Lilliput mussel (*Toxolasma cylindrellus*)
Rabbitsfoot mussel (*Quadrula cylindrica cylindrica*)
Rayed bean (*Villosa fabalis*)
Rough rabbitsfoot (*Quadrula cylindrica strigillata*)
Scaleshell mussel (*Leptodea leptodon*)
Sheepnose (*Plethobasus cyphus*)
Shiny pigtoe (*Fusconaia cor*)
Slabside pearlymussel (*Pleurobema dolabelloides*)
Snuffbox mussel (*Epioblasma triquetra*)
Southern acornshell mussel (*Epioblasma othcaloogenis*)
Southern pigtoe mussel (*Pleurobema georgianum*)
Spectacle mussel (*Cumberlandia monodonta*)
Tan riffleshell mussel (*Epioblasma florentina walkeri*)
Triangular kidneyshell mussel (*Ptychobranthus greenii*)
Tubercled blossom mussel (*Epioblasma torulosa torulosa*)
Turgid blossom mussel (*Epioblasma turgidula*)
White wartysack mussel (*Plethobasus cicatricosus*)
Winged mapleleaf mussel (*Quadrula fragosa*)
Yellow blossom mussel (*Epioblasma florentina florentina*)

Fish Species

Spotfin chub (*Erimonax monachus*)

Slender chub (*Erimystax cahnii*)
 Relict darter (*Etheostoma chienense*)
 Tuxedo darter (*Etheostoma lemniscatum*)
 Marbled darter (*Etheostoma marmorpinnum*)
 Duskytail darter (*Etheostoma percnum*)
 Citico darter (*Etheostoma sitikuense*)
 Snail darter (*Percina tanasi*)
 Diamond darter (*Crystallaria cincotta*)
 Cumberland darter (*Etheostoma susanae*)
 Palezone shiner (*Notropis albizonatus*)
 Blackside dace (*Phoxinus cumberlandensis*)

Permit Application Number: TE48833A

Applicant: Brian Carver, Tennessee Tech University

The applicant requests a permit renewal to take (capture, handle, radio-tag, and release) the Indiana bat (*Myotis sodalis*) and gray bat (*M. grisescens*) in the State of Tennessee. Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Permit Application Number: TE07730A

Applicant: Kiersten Fuchs, Redwing Ecological Services, Inc.

The applicant requests a permit amendment to add the rabbitsfoot mussel (*Quadrula cylindrica cylindrica*), fluted kidneyshell mussel (*Ptychobranchus subtentum*), and the slabside pearlymussel (*Pleurobema dolabelloides*) to their permit. The requested amendment would also add personnel to their permit. Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Permit Application Number: TE38085B

Applicant: Keith A. Johnson, Mountain State Biosurveys, LLC

The applicant requests a permit to take (survey, capture and release; non-destructive sampling) the Indiana bat (*Myotis sodalis*) in the States of Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, Puerto Rico/Virgin Islands, South Carolina, Tennessee, Ohio, Indiana, Illinois, Michigan, Wisconsin, Minnesota, Ohio, and Missouri. Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Permit Application Number: TE2373A

Applicant: Virgil Brack, Environmental Solutions and Innovations

The applicant requests a permit amendment to take (survey, capture and release; non-destructive sampling) the

Rabbitsfoot mussel (*Quadrula cylindrica cylindrica*) in the States of Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, Puerto Rico/Virgin Islands, South Carolina, Tennessee, Ohio, Indiana, Illinois, Michigan, Wisconsin, Minnesota, Ohio, and Missouri. Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Permit Application Number: TE73584A

Applicant: Brian Anderson, Illinois Natural History Survey

The applicant requests a permit amendment to take (survey, capture and release; non-destructive sampling) the scaleshell mussel (*Leptodea leptodon*), rabbitsfoot mussel (*Quadrula cylindrica cylindrica*), and spectaclecase mussel (*Cumberlandia monodonta*) in the State of Illinois. Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Permit Application Number: TE06801A

Applicant: Neil Bossart, Pittsburgh Wildlife and Environmental, Inc.

The applicant requests a permit amendment to add personnel to their permit. Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Permit Application Number: TE40160B

Applicant: Daniel J. Call, Environmental Research and Information Analysts, LLC

The applicant requests a permit to take (survey, capture and release; nondestructive sampling) the fat pocketbook mussel (*Potamilus capax*), Higgin's eye pearlymussel (*Lampsilis higginsii*), scaleshell mussel (*Leptodea leptodon*), sheepnose mussel (*Plethobasus cyphus*), spectaclecase mussel (*Cumberlandia monodonta*), and winged mapleleaf mussel (*Quadrula fragosa*) in the Upper Mississippi River in the State of Illinois. Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Permit Application Number: TE02344A

Applicant: Donald C. Fortenbery, Mainstream Commercial Divers, Inc.

The applicant requests a permit amendment to add the rabbitsfoot mussel (*Quadrula cylindrica cylindrica*), finelined pocketbook mussel (*Lampsilis altalis*), southern clubshell mussel (*Pleurobema decisum*), and triangular kidneyshell mussel (*Ptychobranchus greenii*) to their permit. The requested amendment

would also add personnel to the permit. Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Request for Public Comments

We seek public review and comments on these permit applications. Please refer to the permit number when you submit comments. Comments and materials we receive are available for public inspection, by appointment, during normal business hours at the address shown in the **ADDRESSES** section. 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: July 30, 2014.

Lynn M. Lewis,

Assistant Regional Director, Ecological Services, Midwest Region.

[FR Doc. 2014-18589 Filed 8-5-14; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R3-ES-2014-N122;
 FXES11120300000-145-FF03E00000]

Notice of Availability of Draft Habitat Conservation Plan; Receipt of Application for Incidental Take Permit; Pioneer Trail Wind Farm, LLC

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: Pursuant to the Endangered Species Act (ESA) and the National Environmental Policy Act (NEPA), we, the U.S. Fish and Wildlife Service (Service), have received an incidental take permit (ITP) application, draft habitat conservation plan (HCP), and a draft Implementing Agreement (IA) from Pioneer Trail Wind Farm, LLC (applicant), located in Ford and Iroquois Counties, Illinois. If approved, the ITP would authorize incidental take of two species of bats (covered species): the Indiana bat, a federally endangered species, and northern long-eared bat, proposed for Federal listing under the ESA. In accordance with the NEPA, the Service has prepared a draft Environmental Assessment (EA) in response to the permit application. We

invite public comment on the ITP application, draft HCP, draft IA, and draft EA.

DATES: To ensure consideration, please send your written comments on or before September 22, 2014.

ADDRESSES: Send written comments via U.S. mail to the Field Supervisor, U.S. Fish and Wildlife Service, Rock Island Field Office, 1511 47th Avenue, Moline, IL 61265; by facsimile to 309-757-5807; or by electronic mail to RockIsland@fws.gov.

FOR FURTHER INFORMATION CONTACT: Amber Schorg, 309-757-5800, extension 222.

SUPPLEMENTARY INFORMATION:

Introduction

Pursuant to section 10(a)(1)(B) of the Endangered Species Act (ESA; 16 U.S.C. 1531 *et seq.*) and the National Environmental Policy Act (NEPA; 42 U.S.C. 4321, *et seq.*), we, the U.S. Fish and Wildlife Service (Service), have received an application from Pioneer Trail Wind Farm, LLC (applicant), located in Ford and Iroquois Counties, Illinois, for an incidental take permit (ITP) under the ESA. If approved, the ITP would authorize incidental take of two species of bats (covered species): the federally endangered Indiana bat (*Myotis sodalis*) and northern long-eared bat (*Myotis septentrionalis*), a species proposed for Federal listing under the ESA. The application includes a draft habitat conservation plan (HCP) and a draft Implementing Agreement (IA). Those documents describe the actions and measures the applicant will take to minimize, mitigate, and monitor take of covered species, and the assurances the applicant will provide should the ITP be issued. In accordance with the NEPA, the Service has prepared a draft Environmental Assessment (EA) in response to the ITP application. We invite public comment on the application, draft HCP, draft IA, and draft EA.

Background

Section 9 of the ESA and its implementing regulations prohibit the "take" of animal species listed as endangered or threatened. Take is defined under the ESA as to "harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect listed animal species, or to attempt to engage in such conduct" (16 U.S.C. 1538). However, under section 10(a) of the ESA, the Service may issue permits to authorize incidental take of listed species. "Incidental take" is defined by the ESA as take that is incidental to, and not the

purpose of, carrying out an otherwise lawful activity.

Requested Permit

The applicant is seeking a permit for incidental take of three individual Indiana bats and two individual northern long-eared bats (hereafter, "covered species") per year; such take may result from operation, maintenance, and decommissioning of an existing 94-turbine wind facility over a 43-year period. The ITP would also cover potential impacts associated with species mitigation, which would include gating and stabilization of high-priority Indiana bat hibernacula, and protection, restoration, enhancement, and long-term management of summer habitat for both species. While the exact location of land proposed as summer habitat mitigation has yet to be finalized, it is likely to occur in Alexander, Champaign, Ford, Hardin, and/or Vermillion Counties, Illinois.

Before the Service can issue a permit to the applicant, it must first confirm that:

- Take will be incidental to an otherwise lawful activity.
- The applicant will, to the maximum extent practicable, minimize and mitigate the impacts of such taking.
- The applicant will ensure that adequate funding for the plan will be provided.
- The taking will not appreciably reduce the likelihood of the survival and recovery of the overall species in the wild.
- Other measures required by the Service in the plan will be met, and there are assurances that the plan will be implemented.

Request for Comments

The Service invites comments and suggestions from all interested parties on the draft documents associated with the permit application. In particular, comments and suggestions regarding whether the draft HCP sufficiently minimizes and mitigates potential impacts associated with take of covered species and any additional information pertinent to evaluation of NEPA alternatives and impacts associated with the proposed federal action, would be appreciated.

Public Availability of Comments

Written comments we receive become part of the public record associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that the entire comment, including your personal

identifying information, may be made available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

We provide this notice under section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.22), and NEPA (42 U.S.C. 4371 *et seq.*) and its implementing regulations (40 CFR 1506.6; 43 CFR Part 46).

Dated: June 25, 2014.

Lynn Lewis,

Assistant Regional Director, Ecological Services, Midwest Region.

[FR Doc. 2014-18590 Filed 8-5-14; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAZ910000.14X.L12100000.XP0000.6100.241A]

State of Arizona Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM), Arizona Resource Advisory Council (RAC) will meet in Phoenix, Arizona, as indicated below.

DATES: The Arizona RAC Business meeting will take place September 10, 2014, from 8:30 a.m. to 3:30 p.m.

ADDRESSES: The meeting will be held at the BLM Arizona State Office located at One North Central Avenue, Suite 800, Phoenix, Arizona 85004.

FOR FURTHER INFORMATION CONTACT: Dorothea Boothe, Arizona RAC Coordinator at the Bureau of Land Management, Arizona State Office, One North Central Avenue, Suite 800, Phoenix, Arizona 85004-4427, 602-417-9504. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 15-member Council advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with public land management in Arizona. Planned agenda items include: A welcome and introduction of Council members; BLM State Director's Update on BLM Programs and Issues; BLM Feedback on RAC Recommendations on Department of the Interior Themes; Value of Friends' Groups and Partnership Strategy; Reports by the RAC Working Groups; RAC Questions on BLM District Manager Reports; Recognition Ceremony and other items of interest to the RAC. Members of the public are welcome to attend the RAC Business meeting. A public comment period is scheduled from 11:00 a.m. to 11:30 a.m. for any interested members of the public who wish to address the Council on BLM programs and business. Depending on the number of persons wishing to speak and time available, the time for individual comments may be limited. Written comments may also be submitted during the meeting for the RAC's consideration. The final meeting agenda will be available two weeks prior to the meeting and posted on the BLM Web site at: <http://www.blm.gov/az/st/en/res/rac.html>. Additionally, directions to the meeting site and parking information may be found on the BLM Web site at: http://www.blm.gov/az/st/en/res/pub_room/location.html. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the RAC Coordinator listed above no later than two weeks before the start of the meeting.

Under the Federal Lands Recreation Enhancement Act, the RAC has been designated as the Recreation RAC (RRAC) and has the authority to review all BLM and Forest Service recreation fee proposals in Arizona. The RRAC will not review recreation fee program proposals at this meeting.

Raymond Suazo,
Arizona State Director.

[FR Doc. 2014-18595 Filed 8-5-14; 8:45 am]

BILLING CODE 4310-32-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLOR-936000-L14300000-ET0000-14XL1109AF; HAG-14-0049; OR-19024]

Public Land Order No. 7827; Partial Withdrawal Revocation, Power Site Reserve No. 24, Oregon

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order partially revokes a withdrawal created by an Executive Order dated July 2, 1910, insofar as it affects approximately 33.05 acres of public land withdrawn for protection of water power values by Power Site Reserve No. 24. This order also opens the land for conveyance by exchange, pursuant to the authority of Section 1754 of the Omnibus Public Land Management Act of 2009.

DATE: *Effective Date:* August 6, 2014.

FOR FURTHER INFORMATION CONTACT: Jenice Prutz, at the Bureau of Land Management, Oregon State Office, P.O. Box 2965, Portland, OR 97208-2965; or by telephone, 503-808-6163. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 to contact the above individual. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The subject land has been identified for conveyance by land exchange to the Confederated Tribes of the Warm Springs Reservation of Oregon pursuant to the Omnibus Public Land Management Act of 2009 (123 Stat. 1049), and therefore will not be restored to the public land laws. Additionally, the land is located within the designated boundary of the John Day Wild and Scenic River, withdrawn pursuant to the National Wild and Scenic Rivers System Act (16 U.S.C. 1271 et seq), and is not open to hydropower development.

Order

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1714), and pursuant to the determination by the Federal Energy Regulatory Commission in DV13-3-000, it is ordered as follows:

1. The withdrawal created by the Executive Order dated July 2, 1910,

which established Power Site Reserve No. 24, is hereby revoked insofar as it affects the following described land:

Willamette Meridian

T. 8 S., R. 19 E.,

Sec. 3, lots 8 and 9.

The area described contains 33.05 acres in Wheeler County.

2. At 9 a.m. on August 6, 2014, the land described in Paragraph 1 is hereby open to conveyance pursuant to the authority under Section 1754 of the Act of March 20, 2009 (123 Stat. 1049).

Dated: July 20, 2014.

Janice M. Schneider,

Assistant Secretary—Land and Minerals Management.

[FR Doc. 2014-18613 Filed 8-5-14; 8:45 am]

BILLING CODE 4310-33-P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR04073000, XXXR4081X3, RX.05940913.7000000]

Notice of Public Meeting for the Glen Canyon Dam Adaptive Management Work Group

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice.

SUMMARY: The Glen Canyon Dam Adaptive Management Work Group (AMWG) makes recommendations to the Secretary of the Interior concerning Glen Canyon Dam operations and other management actions to protect resources downstream of Glen Canyon Dam, consistent with the Grand Canyon Protection Act. The AMWG meets two to three times a year.

DATES: The meeting will be held on Wednesday, August 27, 2014, from approximately 9:30 a.m. to approximately 5:30 p.m.; and Thursday, August 28, 2014, from approximately 8:00 a.m. to approximately 3 p.m.

ADDRESSES: The meeting will be held at the Little America Hotel Flagstaff, Ballroom B, 2515 E. Butler Ave, Flagstaff, AZ 86004.

FOR FURTHER INFORMATION CONTACT: Glen Knowles, Bureau of Reclamation, telephone (801) 524-3781; facsimile (801) 524-3858; email at gknowles@usbr.gov.

SUPPLEMENTARY INFORMATION: The Glen Canyon Dam Adaptive Management Program (GCDAMP) was implemented as a result of the Record of Decision on the Operation of Glen Canyon Dam Final Environmental Impact Statement to comply with consultation

requirements of the Grand Canyon Protection Act (Pub. L. 102–575) of 1992. The GCDAMP includes a Federal advisory committee, the AMWG, a technical work group (TWG), a Grand Canyon Monitoring and Research Center, and independent review panels. The TWG is a subcommittee of the AMWG and provides technical advice and recommendations to the AMWG.

Agenda: The primary purpose of the meeting will be to approve the Fiscal Year 2015–2017 Triennial Budget and Work Plan, and to approve the Water Year 2015 Hydrograph operation for Glen Canyon Dam. The AMWG will receive updates on: (1) The Long-Term Experimental and Management Plan Environmental Impact Statement, (2) current basin hydrology and drought impacts, (3) reports from the Glen Canyon Dam Tribal and Federal Liaisons. The AMWG will also address other administrative and resource issues pertaining to the GCDAMP.

To view a copy of the agenda and documents related to the above meeting, please visit Reclamation's Web site at <http://www.usbr.gov/uc/rm/amp/amwg/mtgs/14aug27/>. Time will be allowed at the meeting for any individual or organization wishing to make formal oral comments. To allow for full consideration of information by the AMWG members, written notice must be provided to Glen Knowles, Bureau of Reclamation, Upper Colorado Regional Office, 125 South State Street, Room 6107, Salt Lake City, Utah, 84138; telephone (801) 524–3781; facsimile (801) 524–3858; email at gknowles@usbr.gov at least five (5) days prior to the meeting. Any written comments received will be provided to the AMWG members.

Public Disclosure of Comments

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: July 31, 2014.

Glen Knowles,

Chief, Adaptive Management Work Group,
Upper Colorado Regional Office, Salt Lake City, Utah.

[FR Doc. 2014–18583 Filed 8–5–14; 8:45 am]

BILLING CODE 4310-MN-P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–923]

Certain Loom Kits for Creating Linked Articles, Institution of Investigation Pursuant to 19 U.S.C. 1337

AGENCY: U.S. International Trade Commission

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on July 1, 2014, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Choon's Design Inc. of Wixom, Michigan. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain loom kits for creating linked articles by reason of infringement of certain claims of U.S. Patent No. 8,485,565 ("the '565 patent"). The complaint further alleges that an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a general exclusion order, or in the alternative a limited exclusion order, and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is 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., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at <http://www.usitc.gov>. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <http://edis.usitc.gov>.

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

Authority: The authority for institution of this investigation is contained in section 337

of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2014).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on July 31, 2014, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain loom kits for creating linked articles by reason of infringement of one or more of claims 2–4 of the '565 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is:

Choon's Design Inc., 48813 West Road, Wixom, MI 48393.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served: Wangying, No. 301 Chang Chun 2 road #58, Jinhua, Zhejiang, China 322000. Island In The Sun LLC, 175 Courts Lane, Little Rock, AR 72222.

Quality Innovations Inc., 12941 Ramona Boulevard, Suite D, Irwindale, CA 91706.

Yiwu Mengwang Craft & Art Factory, 7F, 2 Unit, No. 290 of Jingfa Road, Yiwu City, Zhejiang, China.

Shenzhen Xuncent Technology Co., Ltd., 2nd Floor-A, Building 1, Building 1, 5, 6, Zhulongtian Road, Fourth Industrial Zone, Shuitian Community, Shiyan Street, Baoan District, Shenzhen, Guangdong, China.

Altatac Inc., 532 Mateo Street, Los Angeles, CA 90013.

My Imports USA LLC, 75 Ethel Road, Edison, NJ 08817.

Jayfinn LLC, 3875 E. Cloudburst Drive, Gilbert, AZ 85297.

Creative Kidstuff, LLC, 3939 46th Street, Minneapolis, MN 55406.

Hongkong Haoguan Plastic Hardware Co., Limited, Industry Part of Gong Chuang Ying, No. 8 of NanDan Road of Nanwan Sreet, Long Gang District, Shenzhen, Guangdong, China 518100. Blinker.com, LLC, 769 Center Street, PMB 58, Fairfax, CA 94930.

Eyyup Arga, 194 Westminster Place, Lodi, NJ 07644.

Itcoolnomore, Room 401, Unit 3, Building 15, Xiawan, G 2nd District Yiwu, Jinhua, Zhejiang, China 322000.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW., Suite 401, Washington, DC 20436; and

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: August 1, 2014.

Jennifer D. Rohrbach,

Supervisory Attorney Advisor.

[FR Doc. 2014-18576 Filed 8-5-14; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Amendment Under the Clean Water Act

On July 29, 2014, the Department of Justice lodged with the United States District Court for the Southern District of Iowa a Consent Decree in *United States v. Archer Daniels Midland Company*, Civil Action: 3:14-cv-00089 SMR-RAW.

This civil action asserts claims for penalties and injunctive relief under the Clean Water Act ("CWA") 33 U.S.C. 1251 *et seq.* against Archer Daniels Midland Company ("ADM") regarding its alleged failure to comply with regulations issued under Section 311(j) of the CWA at five oil storage facilities located in the states of Missouri, Nebraska and Iowa. Additionally, this action asserts claims for violation of industrial stormwater permits issued pursuant to Section 402 of the CWA at three of the same five facilities.

The United States seeks injunctive relief and civil penalties intended to deter ADM's further non-compliance with the CWA at the subject facilities.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States v. Archer Daniels Midland Company*, Civil Action: 3:14-cv-00089 SMR-RAW, D.J. Ref. No. 90-5-1-1-10893.

All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

<i>To submit comments:</i>	<i>Send them to:</i>
By email	pubcomment-ees.enrd@usdoj.gov .
By mail	Assistant Attorney General U.S. DOJ—ENRD P.O. Box 7611 Washington, D.C. 20044–7611.

During the public comment period, Consent Decree may be examined and downloaded at this Justice Department Web site: http://www.usdoj.gov/enrd/Consent_Decrees.html. 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 \$6.75 (25 cents per page reproduction cost) payable to the United States Treasury.

Susan M. Akers,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2014-18573 Filed 8-5-14; 8:45 am]

BILLING CODE 4410-15-P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA 2014-047]

Office of Government Information Services (OGIS), Freedom of Information Act (FOIA) Advisory Committee Special Notice; Correction

AGENCY: National Archives and Records Administration.

ACTION: Notice; correction.

SUMMARY: The National Archives and Records Administration published a notice in the **Federal Register** of May 27, 2014, announcing a meeting for the FOIA Advisory Committee. The notice provided incorrect information. This document corrects the errors by providing the correct information.

FOR FURTHER INFORMATION CONTACT: Christa Lemelin, Designated Federal Officer, by mail at the National Archives and Records Administration, Office of Government Information Services, 8601 Adelphi Road—OGIS, College Park, MD 20740-6001; Telephone 202-741-5773; email Christa.Lemelin@nara.gov; or Fax 202-741-5769.

Correction: In FR Doc. 2014-12146, published on May 27, 2014, on page 30184, in the second column, correct the **SUPPLEMENTARY INFORMATION** to read:

The FOIA Advisory Committee was established in accordance with the second U.S. Government National Action Plan and the directive in the FOIA, 5 U.S.C. 552(h)(1)(C), that OGIS "recommend policy changes . . . to improve" FOIA administration. The Committee is governed by the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App. The Committee serves as a deliberative body to advise on improvements to FOIA administration. The Committee studies the current FOIA landscape across the Executive Branch and may recommend legislative action, policy changes or executive action, among other matters. Details regarding the committee and how to submit comments to the Committee are available in the "FOIA Advisory Committee" section of OGIS's Web site, at <https://ogis.archives.gov/foia-advisory-committee.htm>. In addition, OGIS will post updates regarding the Committee to its blog, The FOIA Ombudsman, at <http://blogs.archives.gov/foiablog/>.

Correction: In FR Doc. 2014-12146, published on May 27, 2014, on page 30184, in the second column, correct the **FOR FURTHER INFORMATION CONTACT** to read:

FOR FURTHER INFORMATION CONTACT: Christa Lemelin, Designated Federal

Officer, by mail at the National Archives and Records Administration, Office of Government Information Services, 8601 Adelphi Road—OGIS, College Park, MD 20740–6001; Telephone 202–741–5773; email Christa.Lemelin@nara.gov; or Fax 202–741–5769.

Dated: July 31, 2014.

Patrice Little Murray,

Acting Committee Management Officer.

[FR Doc. 2014–18565 Filed 8–5–14; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Arts Advisory Panel Meeting

AGENCY: National Endowment for the Arts, National Foundation on the Arts and Humanities.

ACTION: Notice of Meeting.

SUMMARY: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that a meeting of the Arts Advisory Panel to the National Council on the Arts will be held by teleconference as follows (all meetings are Eastern time and ending times are approximate):

Artist Communities (application review): This meeting will be virtual and will be closed.

DATES: August 13, 2014. 2:00 p.m. to 4:00 p.m. This meeting is being held on an emergency basis to address time sensitive issues.

FOR FURTHER INFORMATION CONTACT: Further information with reference to these meetings can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC, 20506; plowitzk@arts.gov, or call 202–682–5691.

SUPPLEMENTARY INFORMATION: The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of February 15, 2012, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of Title 5, United States Code.

Dated: August 1, 2014.

Kathy Plowitz-Worden,

Panel Coordinator, National Endowment for the Arts.

[FR Doc. 2014–18618 Filed 8–5–14; 8:45 am]

BILLING CODE 7537–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2014–0078]

Agency Information Collection Activities: Submission for the Office of Management and Budget (OMB) Review; Comment Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). 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 April 23, 2014.

1. *Type of submission, new, revision, or extension:* Extension.

2. *The title of the information collection:* NRC Form 536, “Operator Licensing Examination Data.”

3. *Current OMB approval number:* 3150–0131.

4. *The form number if applicable:* NRC Form 536.

5. *How often the collection is required:* Annually.

6. *Who will be required or asked to report:* All holders of operating licenses for nuclear power reactors under the provision of Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR), “Domestic Licensing of Production and Utilization Facilities,” except those that have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel. All holders of, or applicants for, a limited work authorization, early site permit, or combined license issued under 10 CFR Part 52, “Licenses, Certifications and Approval for Nuclear Power Plants.”

7. *An estimate of the number of annual responses:* 105.

8. *The estimated number of annual respondents:* 105.

9. *An estimate of the total number of hours needed annually to complete the requirement or request:* 105.

10. *Abstract:* The NRC is requesting renewal of its clearance to annually request all commercial power reactor licensees and applicants for an

operating license to voluntarily send to the NRC: (1) Their projected number of candidates for initial operator licensing examinations; (2) the estimated dates of the examinations; (3) if the examinations will be facility developed or NRC developed, and (4) the estimated number of individuals that will participate in the Generic Fundamentals Examination (GFE) for that calendar year. Except for the GFE, this information is used to plan budgets and resources in regard to operator examination scheduling in order to meet the needs of the nuclear power industry.

The public may examine and have copied for a fee publicly-available documents, including the final supporting statement, at the NRC’s Public Document Room, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. The OMB clearance requests are available at the NRC’s Web site: <http://www.nrc.gov/public-involve/doc-comment/omb/>. The document will be available on the NRC’s home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer listed below by September 5, 2014. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Danielle Y. Jones, Desk Officer, Office of Information and Regulatory Affairs (3150–0131), NEOB–10202, Office of Management and Budget, Washington, DC 20503.

Comments can also be emailed to Danielle_Y_Jones@omb.eop.gov or submitted by telephone at 202–395–1741.

The Acting NRC Clearance Officer is Brenda Miles, telephone: 301–415–7884.

Dated at Rockville, Maryland, this 1st day of August, 2014.

For the Nuclear Regulatory Commission.

Brenda Miles,

Acting NRC Clearance Officer, Office of Information Services.

[FR Doc. 2014–18562 Filed 8–5–14; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–305 and 72–64; NRC–2014–0185]

Exemptions; Issuance: Dominion Energy Kewaunee, Inc.

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption in response to a June 4, 2013, request from Dominion Energy Kewaunee, Inc. (DEK, the licensee), from certain regulatory requirements. The exemption would remove the requirement that a licensed senior operator approve the emergency suspension of security measures for Kewaunee Power Station (KPS) during certain emergency conditions or during severe weather.

ADDRESSES: Please refer to Docket ID NRC-2014-0185 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- Federal Rulemaking Web site: Go to <http://www.regulations.gov> and search for Docket ID NRC-2014-0185. Address questions about NRC dockets to Carol Gallagher; telephone: 301-287-3422; email: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- NRC's Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.

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

FOR FURTHER INFORMATION CONTACT: William Huffman, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2046, email: William.Huffman@nrc.gov.

I. Background

Dominion Energy Kewaunee, Inc. (DEK) is the holder of Renewed Facility License No. DPR-43. The license provides, among other things, that the facility is subject to all rules,

regulations, and orders of the NRC now or hereafter in effect.

The facility consists of a permanently shutdown and defueled pressurized water reactor and a general licensed independent spent fuel storage installation located in Kewaunee County, Wisconsin.

By letter dated February 25, 2013 (ADAMS Accession No. ML13058A065), DEK submitted to the NRC the certification in accordance with Section 50.82(a)(1)(i) of Title 10 of the *Code of Federal Regulations* (10 CFR) indicating it would permanently cease power operations at KPS on May 7, 2013. On May 7, 2013, DEK permanently ceased power operation at KPS. By letter dated May 14, 2013 (ADAMS Accession No. ML13135A209), DEK submitted to the NRC the certification per 10 CFR 50.82(a)(1)(ii) that the reactor vessel at KPS was permanently defueled.

II. Request/Action

Pursuant to 10 CFR 73.5, "Specific exemptions," the licensee has, by letter dated June 4, 2013 (ADAMS Accession No. ML13161A168), requested an exemption from 10 CFR 73.55(p)(1)(i) and 73.55(p)(1)(ii), which otherwise require in part that a licensed senior operator approves the suspension of security measures during certain emergency conditions or during severe weather. Portions of the letter dated June 4, 2013, contain sensitive unclassified non-safeguards information (security-related) and, accordingly, have been withheld from public disclosure. The regulations in 10 CFR 73.55(p)(1)(i) and 73.55(p)(1)(ii), respectively, specify that the suspension of security measures must be approved by, as a minimum, a licensed senior operator, or a licensed senior operator with input from the security supervisor or manager.

The exemption request relates solely to the licensing requirements specified in the regulations for the staff directing suspension of security measures in accordance with 10 CFR 73.55(p)(1)(i) and 73.55(p)(1)(ii). Section 73.55(p)(1)(i) of 10 CFR requires that "suspension of security measures must be approved as a minimum by a licensed senior operator before taking this action"; 10 CFR 73.55(p)(1)(ii) requires that "suspension of security measures must be approved, as a minimum, by a licensed senior operator, with input from the security supervisor or manager, before taking this action."

This exemption would remove the requirement for a licensed senior operator to provide the approval. Instead, the licensee intends the suspension of security measures to be

authorized by a certified fuel handler (CFH), as defined in 10 CFR 50.2.

III. Discussion

Historically, the Commission's security rules have long recognized the potential to suspend security or safeguards measures. In 1986, in its Final Rule, "Miscellaneous Amendments Concerning the Physical Protection of Nuclear Power Plants," 51 FR 27,817 (Aug. 4, 1986), the Commission promulgated 10 CFR 73.55(a), stating in part:

In accordance with § 50.54(x) and (y) of Part 50, the licensee may suspend any safeguards measures pursuant to § 73.55 in an emergency when this action is immediately needed to protect the public health and safety and no action consistent with license conditions and technical specification that can provide adequate or equivalent protection is immediately apparent. This suspension must be approved as a minimum by a licensed senior operator prior to taking the action.

Later, in Proposed Rule, "Decommissioning of Nuclear Power Plants," 60 FR 37,374, (July 20, 1995), the Commission made a number of proposed rule changes to address decommissioning. Among the changes were new regulations that affected § 50.54(x) and (y) by allowing a non-licensed operator called a "Certified Fuel Handler," in addition to a licensed senior operator, to authorize protective steps. Specifically, when proposing the rule addressing the role of the CFH during emergencies, the Commission stated:

The Commission is proposing to amend 10 CFR 50.54(y) to permit a certified fuel handler at nuclear power reactors that have permanently ceased operations and permanently removed fuel from the reactor vessel, subject to the requirements of § 50.82(a) and consistent with the proposed definition of "Certified Fuel Handler" specified in § 50.2, to make these evaluations and judgments. A nuclear power reactor that has permanently ceased operations and no longer has fuel in the reactor vessel does not require a licensed individual to monitor core conditions. A certified fuel handler at a permanently shutdown and defueled nuclear power reactor undergoing decommissioning is an individual who has the requisite knowledge and experience to evaluate plant conditions and make these judgments.

In the final rule, 61 FR 39,278 (July 29, 1996), the Commission added the following definition to 10 CFR 50.2: "Certified fuel handler means, for a nuclear power reactor facility, a non-licensed operator who has qualified in accordance with a fuel handler training program approved by the Commission." However, the Decommissioning Rule did not propose or make parallel

changes to 10 CFR 73.55(a), and did not discuss the role of a non-licensed certified fuel handler.

In the Final Rule, "Power Reactor Security Requirements," 74 FR 13,926 (March 27, 2009), the NRC relocated and split the security suspension requirements from 10 CFR 73.55(a) to 10 CFR 73.55(p)(1)(i) and (p)(1)(ii). CFHs were not discussed in the rulemaking, so the requirements of 10 CFR 73.55(p) to use a licensed senior operator remains, even for a site that otherwise no longer has an operating reactor.

However, pursuant to 10 CFR 73.5, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of this 10 CFR Part 73 as it determines are authorized by law and will not endanger life or property or the common defense and security, and are otherwise in the public interest.

A. Authorized by Law

The exemption from 10 CFR 73.55(p)(1)(i) and 10 CFR 73.55(p)(1)(ii) would remove the requirement that a licensed senior operator approve the suspension of security measures, under certain emergency conditions or severe weather. The licensee intends to align these regulations with 10 CFR 50.54(y) by using the authority of a non-licensed CFH in place of a licensed senior operator to approve the suspension of security measures during certain emergency conditions or during severe weather.

Per 10 CFR 73.5, the Commission's regulations allow the Commission to grant exemptions from the regulations in 10 CFR Part 73 as the Commission determines are authorized by law. The NRC staff has determined that granting of the licensee's proposed exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, or other laws. Therefore, the exemption is authorized by law.

B. Will Not Endanger Life or Property or the Common Defense and Security

Removing the requirement to have a licensed senior operator approve suspension of security measures during emergencies or severe weather will not endanger life or property or the common defense and security for the reasons described below.

First, 10 CFR 73.55(p)(2) continues to require that "[s]uspended security measures must be reinstated as soon as conditions permit."

Second, the suspension for non-weather emergency conditions under 10 CFR 73.55(p)(1)(i) will continue to be invoked only "when this action is immediately needed to protect the

public health and safety and no action consistent with license conditions and technical specifications that can provide adequate or equivalent protection is immediately apparent." Thus, the underlying purpose of 10 CFR 73.55(p)(1)(i) will still be to protect public health and safety even after the exemption is granted.

Third, the suspension for severe weather under 10 CFR 73.55(p)(1)(ii) will continue to be used only when "the suspension of affected security measures is immediately needed to protect the personal health and safety of security force personnel and no other immediately apparent action consistent with the license conditions and technical specifications can provide adequate or equivalent protection." The requirement to receive input from the security supervisor or manager will remain. The underlying purpose of 10 CFR 73.55(p)(1)(ii) will continue to be to protect the health and safety of the security force.

Additionally, by letter dated May 12, 2014, the NRC staff approved DEK's CFH training and retraining program for the KPS facility. The NRC staff found that, among other things, the program addresses the safe conduct of decommissioning activities, safe handling and storage of spent fuel, and the appropriate response to plant emergencies. Because the CFH is sufficiently trained and qualified under an NRC-approved program, the NRC staff considers a CFH to have sufficient knowledge of operational and safety concerns such that there will be no adverse effects or undue risk to the public health and safety as a result of the suspension of security measures during the emergencies or severe weather.

In addition, the exemption does not reduce the overall effectiveness of the physical security plan and has no adverse impact on DEK's ability to physically secure the site or protect special nuclear material at KPS, and thus would not have an effect on the common defense and security. The NRC staff has concluded that the exemption would not reduce security measures currently in place to protect against radiological sabotage. Therefore, removing the requirement for a licensed senior operator to approve the suspension of security measures in an emergency or during severe weather so that suspension of security measures can be authorized by CFH does not adversely affect public health and safety issues or the assurance of the common defense and security.

C. Is Otherwise in the Public Interest

DEK's proposed exemption would remove the requirement that a licensed senior operator approve suspension of security measures in an emergency when "immediately needed to protect the public health and safety" or during severe weather when "immediately needed to protect the personal health and safety of security force personnel." Without the exemption, the licensee cannot implement changes to its security plan to authorize a CFH to approve temporary suspension of security regulations during an emergency or severe weather comparable to the authority given to the CFH by the Commission when it promulgated 10 CFR 50.54(y). Instead, the regulations would continue to require that a licensed senior operator be available to make decisions for a permanently shutdown plant, even though KPS no longer requires a licensed senior operator. It is unclear how the licensee would implement emergency or severe weather suspensions of security measures without a licensed senior operator. This exemption is in the public interest for two reasons. First, without the exemption, there is uncertainty about how the licensee will invoke temporary suspension of security matters that may be needed for protecting public health and safety or the safety of the security forces during emergencies and severe weather. Additionally, the consistent and efficient regulation of nuclear power plants serves the public interest by assuring consistency between the security regulations in 10 CFR Part 73 and the operating reactor regulations in 10 CFR Part 50, and the requirements concerning licensed operators in 10 CFR Part 55. Accordingly, the NRC staff concludes that exempting requirements to obtain approval from a licensed senior operator, who is not otherwise required for a permanently shutdown and defueled reactor, before taking steps to protect the public health and safety, or to protect the safety of the security force, is in the public interest.

D. Environmental Considerations

NRC approval of the exemption to security requirements belongs to a category of actions that the Commission, by rule or regulation, has declared to be a categorical exclusion, after first finding that the category of actions does not individually or cumulatively have a significant effect on the human environment. Specifically the exemption is categorically excluded from further analysis under 10 CFR 51.22(c)(25).

Under 10 CFR 51.22(c)(25), granting of an exemption from the requirements of any regulation of Chapter I to 10 CFR is a categorical exclusion provided that (i) there is no significant hazards consideration; (ii) there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; (iii) there is no significant increase in individual or cumulative public or occupational radiation exposure; (iv) there is no significant construction impact; (v) there is no significant increase in the potential for or consequences from radiological accidents; and (vi) the requirements from which an exemption is sought involve: Safeguard plans, and materials control and accounting inventory scheduling requirements; or involve other requirements of an administrative, managerial, or organizational nature.

The Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation, has determined that approval of the exemption request involves no significant hazards consideration because removing the requirement to have a licensed senior operator approve the security suspension at a defueled shutdown power plant does not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The exempted security regulation is unrelated to any operational restriction. Accordingly, there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; and no significant increase in individual or cumulative public or occupational radiation exposure. The exempted regulation is not associated with construction, so there is no significant construction impact. The exempted regulation does not concern the source term (i.e., potential amount of radiation in an accident), nor mitigation. Thus, there is no significant increase in the potential for, or consequences of, a radiological accident. The requirement to have a licensed senior operator approve departure from security actions may be viewed as involving either safeguards, materials control, or managerial matters.

Therefore, pursuant to 10 CFR 51.22(b) and 51.22(c)(25), no environmental impact statement or environmental assessment need be prepared in connection with the approval of this exemption request.

IV. Conclusions

Accordingly, the Commission has determined that, pursuant to 10 CFR 73.5, the exemption is authorized by law and will not endanger life or property or the common defense and security, and is otherwise in the public interest. Therefore, the Commission hereby grants DEK exemption from the requirements of 10 CFR 73.55(p)(1)(i) and 10 CFR 73.55(p)(1)(ii), which otherwise would require suspension of security measures during emergencies and severe weather, respectively, to be approved by a licensed senior operator. The exemption is effective upon issuance.

Dated at Rockville, Maryland, this 25th day of July 2014.

For the Nuclear Regulatory Commission.

A. Louise Lund,

Acting Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2014-18631 Filed 8-5-14; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 40-9075-MLA]

Atomic Safety and Licensing Board; Notice (Regarding Weapons at Atomic Safety and Licensing Board Proceedings)

Before Administrative Judges: William J. Froehlich, Chairman, Dr. Richard F. Cole, Dr. Mark O. Barnett.

In the Matter of Powertech USA, Inc. (Dewey-Burdock In Situ Uranium Recovery Facility).

ASLBP No. 10-898-02-MLA-BD01.

July 31, 2014.

Take notice that the rules regarding weapons in the U.S. Courthouse and United States Federal Building in the State of South Dakota shall apply to all proceedings conducted by the Atomic Safety and Licensing Board of the U.S. Nuclear Regulatory Commission.

No person other than federal law enforcement, Fall River County Sheriff's Department, Hot Springs Police Department, Rapid City Police Department or other authorized law enforcement organization while performing official duties, shall wear or otherwise carry a firearm, edged weapon, impact weapon, electronic control device, chemical weapon, ammunition, or other dangerous weapon into the Limited Appearance Sessions scheduled at the Mueller Civic Center on August 18, 2014 or the evidentiary hearing scheduled at the

Hotel Alex Johnson, beginning on August 19, 2014.

That this order shall not apply to local law enforcement officers responding to a call for assistance from within the Mueller Civic Center or the Hotel Alex Johnson.

It is so *ordered*.

Dated: July 31, 2014.

The Atomic Safety and Licensing Board,
Rockville, Maryland.

William J. Froehlich,

Chair, Administrative Judge.

[FR Doc. 2014-18628 Filed 8-5-14; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2012-0220]

Standard Review Plan for License Applications for Fuel Cycle Facilities

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft NUREG; extension of comment period.

SUMMARY: On June 5, 2014, the U.S. Nuclear Regulatory Commission (NRC) solicited comments on draft NUREG-1520, Revision 2, titled "Standard Review Plan [SRP] for License Applications for Fuel Cycle Facilities." The public comment period was originally scheduled to close on September 3, 2014. The NRC has decided to extend the public comment period on this document to allow more time for members of the public to develop and submit their comments.

DATES: The due date for comments requested in the document published on June 5, 2014 (79 FR 32579) is extended. Comments must be filed no later than November 3, 2014. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- Federal Rulemaking Web site: Go to <http://www.regulations.gov> and search for Docket ID NRC-2012-0220. Address questions about NRC dockets to Carol Gallagher; telephone: 301-287-3422; email: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- Mail comments to: Cindy Bladey, Office of Administration, Mail Stop:

3WFN, 06–A44, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: Soly I. Soto, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–287–9076, email: Soly.Soto@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2012–0220 when contacting the NRC about the availability of information regarding NUREG–1520. You may obtain publicly-available information related to this action by the following methods:

- Federal Rulemaking Web site: Go to <http://www.regulations.gov> and search for Docket ID NRC–2012–0220.
- NRC’s Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “ADAMS Public Documents” and then select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to pdr.resource@nrc.gov. Draft NUREG–1520, Revision 2, is available in ADAMS under Accession No. ML14150A417.
- NRC’s PDR: You may examine and purchase copies of public documents at the NRC’s PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2012–0220 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit

comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Further Information

On June 5, 2014 (79 FR 32579), the NRC solicited comments on draft NUREG–1520, Revision 2, titled “Standard Review Plan for License Applications for Fuel Cycle Facilities.” This SRP provides NRC staff guidance for reviewing and evaluating the safety, health, security and environmental protection aspects of applications for licenses to possess and use special nuclear material (SNM) at fuel cycle facilities. The public comment period originally was scheduled to close on September 3, 2014. However, the NRC is planning to schedule a public meeting around September 2014 and has decided to extend the public comment period on this document to allow more time for members of the public to incorporate information shared at this public meeting as they develop and submit their comments. The deadline for submitting comments will be extended to November 3, 2014. A public meeting notice will be published in the future to announce the day of the meeting.

Dated at Rockville, Maryland, this 29th day of July 2014.

For the Nuclear Regulatory Commission.

Marissa G. Bailey,

Director, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2014–18622 Filed 8–5–14; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–31194]

Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940

July 31, 2014.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company

Act of 1940 for the month of July 2014. A copy of each application may be obtained via the Commission’s Web site by searching for the file number, or for an applicant using the Company name box, at <http://www.sec.gov/search/search.htm> or by calling (202) 551–8090. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by writing to the SEC’s Secretary at the address below and serving the relevant applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on August 26, 2014, and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer’s interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

FOR FURTHER INFORMATION CONTACT: Diane L. Titus at (202) 551–6810, SEC, Division of Investment Management, Chief Counsel’s Office, 100 F Street NE., Washington, DC 20549–8010.

JP Morgan Mutual Fund Group [File No. 811–5151]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. On November 29, 2012, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of approximately \$35,774 incurred in connection with the liquidation were paid by applicant.

Filing Dates: The application was filed on June 2, 2014, and amended on July 24, 2014.

Applicant’s Address: 270 Park Ave., New York, NY 10017.

Tortoise North American Energy Corp. [File No. 811–21700]

Tortoise Energy Capital Corp. [File No. 811–21725]

Summary: Each applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicants transferred their assets to Tortoise Energy Infrastructure Corporation and on June 23, 2014, made distributions to their shareholders based on net asset value. Expenses of approximately \$475,000 incurred in connection with each reorganization were paid by the

relevant applicant and the acquiring fund.

Filing Date: The applications were filed on June 25, 2014.

Applicants' Address: 11550 Ash St., Suite 300, Leawood, KS 66211.

Goldman Sachs Credit Strategies Fund [File No. 811-22280]

Summary: Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant transferred its assets to Goldman Sachs Long Short Credit Strategies Fund, a series of Goldman Sachs Trust, and on March 21, 2014, made a distribution to its shareholders based on net asset value. Expenses of \$320,000 incurred in connection with the reorganization were paid by applicant and Goldman Sachs Asset Management, L.P., applicant's investment adviser.

Filing Date: The application was filed on July 7, 2014.

Applicant's Address: 71 Wacker Dr., Chicago, IL 60606.

Keystone Mutual Funds [File No. 811-21890]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant transferred its assets to MainStay Cornerstone Growth Fund, a series of MainStay Funds Trust, and on January 11, 2013, made a distribution to its shareholders based on net asset value. Expenses of \$253,488 incurred in connection with the reorganization were paid by Cornerstone Capital Management, LLC and/or Cornerstone Capital Management Inc., applicant's investment adviser.

Filing Dates: The application was filed on March 10, 2014, and amended on July 8, 2014.

Applicant's Address: 3600 Minnesota Dr., Suite 70, Edina, MN 55435.

First Variable Rate Fund for Government Income [File No. 811-2633]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant transferred its assets to Calvert Fund, and on October 25, 2013, made a distribution to its shareholders, based on net asset value. Expenses of \$38,541 incurred in connection with the reorganization were paid by applicant.

Filing Dates: The application was filed on November 21, 2013, and amended on July 11, 2014.

Applicant's Address: 4550 Montgomery Ave., Suite 1125N, Bethesda, MD 20814.

Eclipse Funds Inc. [File No. 811-6175]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant transferred its assets to corresponding series of MainStay Funds Trust, and on May 24, 2013, made a distribution to its shareholders based on net asset value. Expenses of \$8,502 incurred in connection with the reorganization were paid by applicant.

Filing Dates: The application was filed on April 30, 2014, and amended on July 16, 2014.

Applicant's Address: 51 Madison Ave., New York, NY 10010.

Oppenheimer Diversified Commodity Strategies Fund [File No. 811-22689]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company.

Applicant has never made a public offering of its securities and does not propose to make a public offering or engage in business of any kind.

Filing Dates: The application was filed on July 15, 2014, and amended on July 21, 2014.

Applicant's Address: 6803 Tucson Way, Centennial, CO 80112.

Scotia Institutional Funds [File No. 811-21913]

Summary: Applicant seeks an order declaring that it has ceased to be an investment company. Applicant transferred the assets of its series, JOHCM Emerging Markets Opportunities Fund, JOHCM Global Equity Fund and JOHCM International Select Fund, to corresponding series of Advisers Investment Trust, and on November 15, 2013, made distributions to its shareholders based on net asset value. Applicant transferred the assets of its Smith Group Large Cap Core Growth Fund series to a corresponding series of Managed Portfolio Series, and on February 21, 2014, made a distribution to its shareholders based on net asset value. Applicant transferred the assets of its Mount Lucas U.S. Focused Equity Fund series to a corresponding series of Fund Vantage Trust, and on March 24, 2014, made a distribution to its shareholders based on net asset value. Applicant transferred the asset of its Dynamic U.S. Growth Fund series, and on March 21, 2014, made a distribution to its shareholders based on net asset value. Expenses of \$694,422 incurred in connection with the reorganizations were paid by JO Hambro Capital Management Limited, Smith Asset Management Group, L.P., Mount Lucas Management LP, and Scotia Institutional Asset Management

US, Ltd., applicant's investment sub-advisers.

Filing Dates: The application was filed on June 4, 2014, and amended on July 23, 2014.

Applicant's Address: 1055 Westlakes Dr., Suite 301, Berwyn, PA 19312.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Kevin M. O'Neill,
Deputy Secretary.

[FR Doc. 2014-18536 Filed 8-5-14; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-72732; File Nos. SR-NYSE-2011-55; SR-NYSEAmex-2011-84]

Self-Regulatory Organizations; New York Stock Exchange LLC; NYSE MKT LLC; Order Granting an Extension to Limited Exemptions From Rule 612(c) of Regulation NMS In Connection With the Exchanges' Retail Liquidity Programs Until March 31, 2015

July 31, 2014.

On July 3, 2012, the Commission issued an order pursuant to its authority under Rule 612(c) of Regulation NMS ("Sub-Penny Rule")¹ that granted the New York Stock Exchange LLC ("NYSE" or "Exchange") and NYSE MKT LLC² ("NYSE MKT" and, together with NYSE, the "Exchanges") limited exemptions from the Sub-Penny Rule in connection with the operation of each Exchange's Retail Liquidity Program ("Programs").³ The limited exemptions were granted concurrently with the Commission's approval of the Exchanges' proposals to adopt their respective Retail Liquidity Programs for one-year pilot terms.⁴ The exemptions were granted coterminous with the effectiveness of the pilot Programs; both the pilot Programs and exemptions are scheduled to expire on July 31, 2014.⁵

¹ 17 CFR 242.612(c).

² At the time it filed the original proposal to adopt the Retail Liquidity Program, NYSE MKT went by the name NYSE Amex LLC. On May 14, 2012, the Exchange filed a proposed rule change, immediately effective upon filing, to change its name from NYSE Amex LLC to NYSE MKT LLC. See Securities Exchange Act Release No. 67037 (May 21, 2012), 77 FR 31415 (May 25, 2012) (SR-NYSEAmex-2012-32).

³ See Securities Exchange Act Release No. 67347, 77 FR 40673 (July 10, 2012) (SR-NYSE-2011-55; SR-NYSEAmex-2011-84) ("Order").

⁴ See *id.*

⁵ The pilot term of the Programs was originally scheduled to end on July 31, 2013, but the Exchanges extended the term for another year, through July 31, 2014. See Securities Exchange Act Release Nos. 70096 (August 2, 2013), 78 FR 48520

The Exchanges now seek to extend the exemptions until March 31, 2015.⁶ The Exchanges' request was made in conjunction with immediately effective filings that extend the operation of the Programs through the same date.⁷ In their request to extend the exemptions, the Exchanges note that the participation in the Programs has increased more recently. Accordingly, the Exchanges have asked for additional time to allow themselves and the Commission to analyze more robust data concerning the Programs, which the Exchanges committed to provide to the Commission.⁸ For this reason and the reasons stated in the Order originally granting the limited exemptions, the Commission finds that extending the exemptions, pursuant to its authority under Rule 612(c) of Regulation NMS, is appropriate in the public interest and consistent with the protection of investors.

Therefore, it is hereby ordered that, pursuant to Rule 612(c) of Regulation NMS, each Exchange is granted a limited exemption from Rule 612 of Regulation NMS that allows it to accept and rank orders priced equal to or greater than \$1.00 per share in increments of \$0.001, in connection with the operation of its Retail Liquidity Program, until March 31, 2015.

The limited and temporary exemptions extended by this Order are subject to modification or revocation if at any time the Commission determines that such action is necessary or appropriate in furtherance of the purposes of the Securities Exchange Act of 1934. Responsibility for compliance with any applicable provisions of the Federal securities laws must rest with the persons relying on the exemptions that are the subject of this Order.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁹

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014-18535 Filed 8-5-14; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-72728; File No. SR-NASDAQ-2014-059]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Order Granting Approval of Proposed Rule Change, as Modified by Amendment No. 1 Thereto, Relating to the Listing and Trading of the Shares of the Global X Commodities ETF of Global X Funds

July 31, 2014.

I. Introduction

On May 28, 2014, The NASDAQ Stock Market LLC ("Exchange" or "Nasdaq") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act" or "Exchange Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to list and trade shares ("Shares") of Global X Commodities Strategy ETF ("Fund") under Nasdaq Rule 5735. The proposed rule change was published for comment in the **Federal Register** on June 16, 2014.³ On June 27, 2014, the Exchange filed Amendment No. 1 to the proposed rule change.⁴ The Commission received no comments on the proposal. This order grants approval of the proposed rule change, as modified by Amendment No. 1 thereto.

II. Description of the Proposal

Nasdaq proposes to list and trade Shares of the Fund under Nasdaq Rule 5735, which governs the listing and trading of Managed Fund Shares on the Exchange. The Shares will be offered by Global X Funds ("Trust"), which was established as a Delaware statutory trust on March 6, 2008.⁵ The Trust is

registered with the Commission as an investment company and has filed a registration statement on Form N-1A ("Registration Statement") with the Commission.⁶ Global X Management Company LLC will be the investment adviser ("Adviser") and administrator ("Administrator") to the Fund. The Fund and the Adviser will contract with an investment sub-adviser ("Sub-Adviser") to provide day-to-day portfolio management of the Fund.⁷ SEI Investments Distribution Company will be the principal underwriter and distributor of the Fund's Shares, and Brown Brothers Harriman ("Custodian") will act as the custodian and transfer agent to the Fund.

The Exchange has made the following representations and statements in describing the Fund and its investment strategy, including other portfolio holdings and investment restrictions.⁸

A. Investment Strategy

According to the Exchange, the Fund will be an actively managed ETF that will seek to achieve a total return that exceeds that of the Credit Suisse Composite Commodities Index ("Benchmark"),⁹ consistent with

exemptive relief under the Investment Company Act of 1940 ("1940 Act") (File No. 812-14241). In compliance with Nasdaq Rule 5735(b)(5), which applies to Managed Fund Shares based on an international or global portfolio, the Trust's application for exemptive relief under the 1940 Act states that the Fund will comply with the federal securities laws in accepting securities for deposits and satisfying redemptions with redemption securities, including that the securities accepted for deposits and the securities used to satisfy redemption requests are sold in transactions that would be exempt from registration under the Securities Act of 1933.

⁶ See Registration Statement on Form N-1A for the Trust dated May 23, 2014 (File No. 811-22209).

⁷ The Exchange represents that the Adviser is not registered as a broker-dealer and is not affiliated with a broker-dealer. In the event (a) the Adviser registers as a broker-dealer or becomes newly affiliated with a broker-dealer; or (b) the Sub-Adviser, any new adviser or new sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, such Adviser, Sub-Adviser, or new adviser or sub-adviser, as the case may be, will implement a fire wall with respect to its relevant personnel or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition of and changes to the portfolio and will be subject to procedures designed to prevent the use and dissemination of material, non-public information regarding the portfolio.

⁸ The Commission notes that additional information regarding the Fund, the Trust, and the Shares, including investment strategies, risks, creation and redemption procedures, fees, portfolio holdings disclosure policies, distributions, and taxes, among other things, can be found in the Notice and the Registration Statement, as applicable. See Notice, *supra* note 3, and Registration Statement, *supra* note 6 and accompanying text, respectively.

⁹ The Exchange represents that the Benchmark is developed, maintained, and sponsored by Credit Suisse International ("CS"), which is not a U.S.

(August 8, 2013) (SR-NYSE-2013-48), and 70100 (August 2, 2013), 78 FR 48535 (August 8, 2013) (SR-NYSEMKT-2013-60). When the pilot term of the Programs was extended, the Commission granted the Exchanges' request to also extend the Sub-Penny Exemption through July 31, 2014. See Securities Exchange Act Release No. 70085 (July 31, 2013), 78 FR 47807 (August 6, 2013).

⁶ See Letter from Martha Redding, Chief Counsel, NYSE, to Kevin M. O'Neill, Deputy Secretary, Securities and Exchange Commission, dated July 30, 2014.

⁷ See Securities and Exchange Commission Release Nos. 72629 (July 16, 2014), 79 FR 42564 (July 22, 2014) (SR-NYSE-2014-35) and 72625 (July 16, 2014), 79 FR 42566 (July 22, 2014) (SR-NYSEMKT-2014-60).

⁸ See Order, *supra* note 3, 77 FR at 40681.

⁹ 17 CFR 200.30-3(a)(83).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 72357 (June 10, 2014), 79 FR 34376 ("Notice").

⁴ In Amendment No. 1, the Exchange clarified which subsections of Nasdaq Rule 5711 are specifically applicable to pooled investment vehicles that invest primarily in commodities and commodity-linked instruments. See *infra* note 10. Because Amendment No. 1 is technical in nature, the Commission believes that Amendment No. 1 is not subject to notice and comment.

⁵ According to the Exchange, the Trust will obtain from the Commission an order granting certain

prudent investment management. The Exchange represents that the Benchmark is a monthly rebalancing, long-only, fully collateralized futures index that offers multi-sector exposure to energy, industrial metals, precious metals, and agricultural commodities. It is a total return index that measures the hypothetical returns on an uncollateralized investment in certain futures contracts, plus the interest that could be earned on the funds committed to a collateralized investment in such contracts. In general, the Fund will pursue its objective by seeking to invest in commodity-linked futures—in similar weightings to the Benchmark—and in other commodity-linked instruments. The Fund's investments in commodity-linked futures and other commodity-linked instruments will be backed by an actively managed, low-volatility portfolio of fixed income instruments. Specifically with respect to the commodity-linked futures and other commodity-linked instruments holdings, the Fund will indirectly invest in exchange-traded futures contracts and exchange-traded commodity-linked instruments¹⁰ (collectively, "Commodities") through a wholly-owned subsidiary controlled by the Fund and organized under the laws of the Cayman Islands ("Subsidiary").¹¹

registered broker-dealer, but is affiliated with a broker-dealer and, with respect to such broker-dealer affiliate, has implemented a fire wall and procedures designed to prevent the illicit use and dissemination of material, non-public information regarding the Benchmark. The Fund will not be sponsored, endorsed, sold, or promoted by CS. CS's only relationship to the Fund will be the licensing of certain service marks and service names of CS and of the Benchmark, which will be determined, composed, and calculated by CS without regard to the Adviser, the Sub-Adviser, or the Fund. CS will have no obligation to take the needs of the Adviser, the Sub-Adviser, or the Fund into consideration in determining, composing, or calculating the Benchmark.

¹⁰ Exchange-traded commodity-linked instruments include: (1) exchange-traded funds ("ETFs") that provide exposure to commodities as would be listed under Nasdaq Rules 5705 and 5735; and (2) pooled investment vehicles that invest primarily in commodities and commodity-linked instruments as would be listed under Nasdaq Rules 5710 and 5711(b), (d), (f), (g), (h), (i), and (j). Such pooled investment vehicles are commonly referred to as "exchange-traded funds," but they are not registered as investment companies because of the nature of their underlying investments. See *infra* note 16 (providing additional information and descriptions about ETFs, in general, and ETFs to be held by the Fund, in particular).

¹¹ The Exchange represents that, as a result of the instruments that will be indirectly held by the Fund, the Adviser will register as a commodity pool operator (as defined in Section 1a(11) of the Commodity Exchange Act) and will also be a member of the National Futures Association ("NFA"). The Exchange represents that the Sub-Adviser will register as a commodity pool operator or commodity trading adviser, as required by the Commodity Futures Trading Commission ("CFTC") regulations and that the Fund and the Subsidiary

The Fund will not be an "index tracking" ETF and will not be required to invest in all of the components of the Benchmark. The Fund will generally seek to hold through the Subsidiary similar instruments to those included in the Benchmark and seek to gain exposure to commodities included in the Benchmark. The Exchange states that the Fund will invest in Commodities only through the Subsidiary.

B. Principal Investments of the Fund

The Fund will be an actively managed ETF that will seek to achieve a total return that exceeds that of the Benchmark. The Exchange states that under normal market conditions,¹² the Fund will invest in Commodities through the Subsidiary. The Fund's investment in the Subsidiary may not exceed 25% of the Fund's total assets. The remainder of the Fund's assets will be invested in: (1) Short-term, investment grade fixed income securities that include U.S. government and agency securities,¹³ corporate debt obligations, and repurchase agreements;¹⁴ (2) money market instruments;¹⁵ (3) ETFs (other than

will be subject to regulation by the CFTC and NFA and additional disclosure, reporting, and recordkeeping rules imposed upon commodity pools.

¹² The Exchange states that the term "under normal market conditions" includes, but is not limited to, the absence of extreme volatility or trading halts in the fixed income markets, futures markets, or the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption, or any similar intervening circumstance.

¹³ These securities will include securities that are issued or guaranteed by the U.S. Treasury, by various agencies of the U.S. government, or by various instrumentalities that have been established or sponsored by the U.S. government. U.S. Treasury obligations are backed by the "full faith and credit" of the U.S. government. Securities issued or guaranteed by federal agencies and U.S. government-sponsored instrumentalities may or may not be backed by the full faith and credit of the U.S. government.

¹⁴ The Exchange states that the Fund intends to enter into repurchase agreements only with financial institutions and dealers believed by the Adviser to present minimal credit risks in accordance with criteria approved by the Trust's Board of Trustees ("Board"). The Adviser will review and monitor the creditworthiness of such institutions and will monitor the value of the collateral at the time the transaction is entered into and at all times during the term of the repurchase agreement.

¹⁵ Money market instruments will include: short-term, high-quality securities issued or guaranteed by non-U.S. governments, agencies, and instrumentalities; non-convertible corporate debt securities with remaining maturities of not more than 397 days that satisfy ratings requirements under Rule 2a-7 under the 1940 Act; money market mutual funds; and deposits and other obligations of

those that are commodity-linked instruments)¹⁶ and other investment companies registered under the 1940 Act, including exchange-traded closed-end funds, that provide exposure to commodities, equity securities, and fixed income securities to the extent permitted under the 1940 Act and any applicable exemptive relief; (4) certain bank instruments;¹⁷ and (5) cash and other cash equivalents. In addition, the Fund may enter into foreign currency transactions on a spot (*i.e.*, cash) basis.

The Exchange represents that the Fund will use the fixed income securities as investments and to collateralize the Subsidiary's commodity exposure on a day-to-day basis.

C. Investments of the Subsidiary

The Exchange represents that, under normal market conditions,¹⁸ the Subsidiary is expected to invest in futures contracts in proportional weights and allocations that are similar to the Benchmark, as well as in other exchange-traded commodity-linked

U.S. and non-U.S. banks and financial institutions. In addition, the Fund may invest in commercial paper, which are short-term unsecured promissory notes. The Fund may invest in commercial paper only if it has received the highest rating from at least one nationally recognized statistical rating organization or, if unrated, has been judged by the Adviser to be of comparable quality.

¹⁶ See *supra* note 10 and accompanying text. In general, an ETF is an investment company registered under the 1940 Act that holds a portfolio of securities. Many ETFs are designed to track the performance of a securities index, including industry, sector, country, and region indexes. The Exchange represents that the ETFs included in the Fund will be listed and traded in the U.S. on registered exchanges. According to the Exchange, the Fund may invest in the securities of ETFs in excess of the limits imposed under the 1940 Act pursuant to exemptive orders obtained by other ETFs and their sponsors from the Commission. In addition, the Fund may invest in the securities of certain other investment companies in excess of the limits imposed under the 1940 Act pursuant to an exemptive order obtained by the Trust and the Adviser from the Commission. See Investment Company Act Release No. 30454 (Apr. 9, 2013) (File No. 812-14079). The ETFs in which the Fund may invest include Index Fund Shares (as described in Nasdaq Rule 5705), Portfolio Depository Receipts (as described in Nasdaq Rule 5705), and Managed Fund Shares (as described in Nasdaq Rule 5735). While the Fund and the Subsidiary may invest in inverse commodity-linked instruments, the Fund and the Subsidiary will not invest in leveraged or inverse leveraged (*e.g.*, 2X or -3X) commodity-linked instruments.

¹⁷ The Fund may invest in certificates of deposit issued against funds deposited in a bank or savings and loan association. In addition, the Fund may invest in bankers' acceptances, which are short-term credit instruments used to finance commercial transactions. The Fund also may invest in bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest.

¹⁸ See *supra* note 12.

instruments.¹⁹ The Subsidiary will have the same investment objective as the Fund; however, unlike the Fund, the Subsidiary may invest without limitation in Commodities. As indicated above, the Benchmark will include, and the Subsidiary will have holdings in, futures contracts that consist of only long positions in Commodities. Therefore, the Fund, through the Subsidiary, will benefit if a security or instrument increases in value. Conversely, the Fund, through the Subsidiary, will be adversely impacted if a security or instrument declines in value. The Fund, through the Subsidiary, may have a higher or lower exposure to any sector or component within the Benchmark at any time.

The Exchange states that the Subsidiary will be advised by the Sub-Adviser²⁰ and that the Fund's investment in the Subsidiary is intended to provide the Fund with exposure to commodity markets within the limits of current federal income tax laws applicable to investment companies, such as the Fund. These federal income tax laws limit the ability of investment companies to invest directly in the derivative instruments. The Subsidiary's investments will provide the Fund with exposure to both domestic and international markets.²¹

¹⁹ According to the Exchange, the Benchmark will include, and the Subsidiary will have holdings in, futures contracts that consist of only long positions in Commodities. Additional information regarding the Benchmark, including the specific commodities underlying the futures contracts included in the Benchmark as of May 23, 2014, can be found in a table in the Notice. See Notice, *supra* note 3, 79 FR 34376, 34378. The table contained in the Notice also provides each instrument's trading hours, exchange, and ticker symbol. See *id.* The Exchange notes that the table is subject to change. As stated above, the Subsidiary will not in all cases invest in the futures contracts included in the Benchmark. The Fund, through the Subsidiary, may have a higher or lower exposure to any sector or component within the Benchmark at any time.

²⁰ The Exchange states that the Subsidiary will not be registered under the 1940 Act and will not be directly subject to its investor protections, except as noted in the Registration Statement. However, the Subsidiary will be wholly-owned and controlled by the Fund. Therefore, the Exchange represents that the Fund's ownership and control of the Subsidiary will prevent the Subsidiary from taking action contrary to the interests of the Fund or its shareholders. The Board will have oversight responsibility for the investment activities of the Fund, including its expected investment in the Subsidiary, and the Fund's role as the sole shareholder of the Subsidiary. The Subsidiary will also enter into separate contracts for the provision of custody, transfer agency, and accounting agent services with the same or with affiliates of the same service providers that provide those services to the Fund.

²¹ The Exchange represents that not more than 10% of the weight (to be calculated as the value of the contract divided by the total absolute notional value of the Subsidiary's futures contracts) of the futures contracts held by the Subsidiary in the aggregate shall consist of instruments whose

D. Investment Restrictions

The Fund intends to qualify for and to elect to be treated as a separate regulated investment company under Subchapter M of the Internal Revenue Code. In addition, while the Fund will be permitted to borrow as permitted under the 1940 Act, the Fund's investments will not be used to seek performance that is the multiple or inverse multiple (*i.e.*, 2X and -3X) of the Fund's Benchmark.

The Fund may not invest more than 25% of the value of its total assets in securities of issuers in any one industry or group of industries. This restriction will not apply to obligations issued or guaranteed by the U.S. government or its agencies or instrumentalities or to securities of other investment companies.

The Subsidiary's shares will be offered only to the Fund, and the Fund will not sell shares of the Subsidiary to other investors. The Fund (other than shares of the Subsidiary) and the Subsidiary will not invest in any non-U.S. equity securities. The Fund will not purchase securities of open-end or closed-end investment companies except in compliance with the 1940 Act or any applicable exemptive relief.

The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment), including securities deemed illiquid by the Adviser.²² The Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of the Fund's net assets are held in illiquid assets. Illiquid assets include securities subject to contractual or other restrictions on resale and other instruments that lack readily available markets as determined in accordance with Commission staff guidance.

principal trading market is not a member of the Intermarket Surveillance Group ("ISG") or is a market with which the Exchange does not have a comprehensive surveillance sharing agreement. The Exchange further represents that all commodity-linked instruments in which the Subsidiary invests will be traded on ISG member markets.

²² In reaching liquidity decisions, the Adviser may consider the following factors: the frequency of trades and quotes for the security; the number of dealers wishing to purchase or sell the security and the number of other potential purchasers; dealer undertakings to make a market in the security; and the nature of the security and the nature of the marketplace trades (*e.g.*, the time needed to dispose of the security, the method of soliciting offers, and the mechanics of transfer).

The Fund will not invest directly in Commodities. The Fund expects to primarily gain exposure to these investments by investing in the Subsidiary. In addition, the Fund and the Subsidiary will not invest in options contracts, swaps, or forward investments.

Additional information regarding the Trust, Fund, and Shares, including investment strategies and restrictions, risks, creation and redemption procedures, fees, portfolio holdings, disclosure policies, distributions and taxes, calculation of net asset value per share ("NAV"), availability of information, trading rules and halts, and surveillance procedures, among other things, can be found in the Notice and the Registration Statement, as applicable.²³

III. Discussion and Commission Findings

After careful review, the Commission finds that the Exchange's proposal to list and trade the Shares is consistent with the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange.²⁴ In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Exchange Act,²⁵ which requires, among other things, that the Exchange's rules be designed to promote just and equitable principles of trade, 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 Commission notes that the Fund and the Shares must comply with the requirements of Nasdaq Rule 5735 to be listed and traded on the Exchange.

The Commission finds that the proposal to list and trade the Shares on the Exchange is consistent with Section 11A(a)(1)(C)(iii) of the Exchange Act,²⁶ which sets forth Congress' finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. Quotation and last-sale information for the Shares will be available via Nasdaq proprietary quote

²³ See Notice, *supra* note 3; see also Registration Statement, *supra* note 6.

²⁴ In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

²⁵ 15 U.S.C. 78f(b)(5).

²⁶ 15 U.S.C. 78k(a)(1)(C)(iii).

and trade services, as well as in accordance with the Unlisted Trading Privileges and the Consolidated Tape Association plans for the Shares. In addition, the Intraday Indicative Value,²⁷ as defined in Rule 5735(c)(3), will be available on the NASDAQ OMX Information LLC proprietary index data service²⁸ and will be updated and widely disseminated by one or more major market data vendors and broadly displayed at least every 15 seconds during the Regular Market Session.²⁹ On each business day, before commencement of trading in Shares in the Regular Market Session on the Exchange, the Fund will disclose on its Web site the identities and quantities of the portfolio of securities, Commodities, and other assets held by the Fund and the Subsidiary (the "Disclosed Portfolio," as defined in Nasdaq Rule 5735(c)(2)) that will form the basis for the Fund's calculation of NAV at the end of the business day.³⁰ In addition, the Custodian, through the National Securities Clearing Corporation, will make available on each business day, prior to the opening of business of the Exchange, the list of the names and quantities of the instruments composing the creation basket, as well as the estimated cash component (if any), for that day. The Fund's NAV will be determined as of the close of trading (normally 4:00 p.m., Eastern Time ("E.T.")) on each day the New York Stock Exchange ("NYSE") is open for business.³¹ Information regarding

market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. The previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. Intra-day executable price quotations on the securities and other assets held by the Fund and the Subsidiary will be available from major broker-dealer firms or on the exchange on which they are traded, as applicable. Intra-day price information on the securities and other assets held by the Fund and the Subsidiary will also be available through subscription services, such as Bloomberg and Thomson Reuters. Specifically, pricing information for Commodities, ETFs (other than Commodities), and closed-end funds will be available on the exchanges on which they are traded and

investments will be generally valued using market valuations. If available, debt securities and money market instruments with maturities of more than 60 days will typically be priced based on valuations provided by independent third-party pricing agents. Such values will generally reflect the last reported sales price if the security is actively traded. The third-party pricing agents may also value debt securities at an evaluated bid price by employing methodologies that utilize actual market transactions, broker-supplied valuations, or other methodologies designed to identify the market value for such securities. Debt obligations with remaining maturities of 60 days or less may be valued on the basis of amortized cost, which approximates market value. If such prices are not available, the security will be valued based on values supplied by independent brokers or by fair value pricing. Futures contracts will be valued at the settlement price established each day by the board or exchange on which they are traded. Redeemable securities issued by U.S. registered open-end investment companies will be valued at the investment company's applicable NAV, with the exception of ETFs, which will be priced as described below. In the case of shares of funds that are not traded on an exchange, a market valuation means such fund's published NAV per share. Equity securities (including exchange-traded commodity-linked instruments, other ETFs, and closed-end funds) listed on a securities exchange, market, or automated quotation system for which quotations are readily available (except for securities traded on the Exchange) will be valued at the last reported sale price on the primary exchange or market on which they are traded on the valuation date (or at approximately 4:00 p.m., E.T. if a security's primary exchange is normally open at that time). If it is not possible to determine the last reported sale price on the relevant exchange or market on the valuation date, the value of the security will be taken to be the most recent mean between the bid and asked prices on such exchange or market on the valuation date. Absent both bid and asked prices on such exchange, the bid price may be used. For securities traded on the Exchange, the Exchange's official closing price will be used. If such prices are not available, the security will be valued based on values supplied by independent brokers or by fair value pricing, as described below. The prices for foreign instruments will be reported in local currency and converted to U.S. dollars using currency exchange rates. Exchange rates will be provided daily by recognized independent pricing agents.

through subscription services. Pricing information for fixed income securities and money market instruments will be available through subscription services and broker-dealer firms. Additionally, the Trade Reporting and Compliance Engine ("TRACE") of the Financial Industry Regulatory Authority ("FINRA") will be a source of price information for certain fixed income securities held by the Fund. Information relating to the Benchmark, including its constituents, weightings, and changes to its constituents will be available on the Web site of CS. The Fund's Web site (www.globalxfunds.com), which will be publicly available prior to the public offering of Shares, will include a form of the prospectus for the Fund and additional data relating to NAV and other applicable quantitative information.

The Commission further believes that the proposal to list and trade the Shares is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading when a reasonable degree of transparency cannot be assured. The Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time. Nasdaq will halt trading in the Shares under the conditions specified in Nasdaq Rules 4120 and 4121, including the trading pauses under Nasdaq Rules 4120(a)(11) and (12). Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable.³² Trading in the Shares also will be subject to Nasdaq Rule 5735(d)(2)(D), which sets forth additional circumstances under which Shares of the Fund may be halted. The Exchange represents that it has a general policy prohibiting the distribution of material, non-public information by its employees. In addition, the Exchange represents that the Adviser is not registered as a broker-dealer and is not affiliated with a broker-dealer.³³ Prior to

³² These reasons may include: (1) The extent to which trading is not occurring in the securities, Commodities, or other assets constituting the Disclosed Portfolio of the Fund and the Subsidiary; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. With respect to trading halts, the Exchange states that it may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund.

³³ See *supra* note 7. The Exchange further represents, among other things, that in the event the

Continued

²⁷ According to the Exchange, the Intraday Indicative Value will reflect an estimated intraday value of the Fund's portfolio (including the Subsidiary's portfolio) and will be based upon the current value of the components of the Disclosed Portfolio.

²⁸ The NASDAQ OMX Global Index Data Service ("GIDS") is a data feed service that provides real-time updates, daily summary messages, and access to widely followed indexes and Intraday Indicative Values for ETFs.

²⁹ Regular Market Session means the trading session from 9:30 a.m. until 4:00 p.m. or 4:15 p.m. See Nasdaq Rule 4120(b)(4)(D).

³⁰ On a daily basis, the Fund will disclose on the Fund's Web site the following information regarding each portfolio holding, as applicable to the type of holding: ticker symbol, CUSIP number, or other identifier, if any; a description of the holding (including the type of holding), the identity of the security, commodity, or other asset or instrument underlying the holding, if any; quantity held (as measured by, for example, par value, notional value, or number of shares, contracts, or units); maturity date, if any; coupon rate, if any; effective date, if any; market value of the holding; and percentage weighting of the holding in the Fund's portfolio. The Web site and information will be publicly available at no charge.

³¹ The NAV of the Fund will be calculated by dividing the value of the net assets of such Fund (i.e., the value of its total assets, less total liabilities) by the total number of outstanding Shares, generally rounded to the nearest cent. According to the Exchange, the Fund's and the Subsidiary's

the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares.

The Exchange represents that trading in the Shares will be subject to existing trading surveillances, administered by both Nasdaq and FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.³⁴ The Exchange further represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. The Exchange states that FINRA, on behalf of the Exchange, will communicate as needed regarding trading in the Shares and in the exchange-traded securities, commodity-linked instruments, and futures contracts held by the Fund and the Subsidiary with other markets and other entities that are members of the ISG and that FINRA may obtain trading information regarding trading in the Shares and in the exchange-traded securities, commodity-linked instruments, and futures contracts held

Sub-Adviser is or becomes a registered broker-dealer or becomes affiliated with a broker-dealer, such Sub-Adviser will implement a fire wall with respect to its relevant personnel or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition of and changes to the portfolio and will be subject to procedures designed to prevent the use and dissemination of material, non-public information regarding the portfolio. *See id.* The Exchange states that an investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 ("Advisers Act"). As a result, the Adviser and the Sub-Adviser and their related personnel are subject to the provisions of Rule 204A-1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A-1 under the Advisers Act. In addition, Rule 206(4)-7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

³⁴ The Exchange states that FINRA surveils trading on the Exchange pursuant to a regulatory services agreement and that the Exchange is responsible for FINRA's performance under this regulatory services agreement.

by the Fund and the Subsidiary from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and in the exchange-traded securities, commodity-linked instruments, and futures contracts held by the Fund and the Subsidiary from markets and other entities that are members of ISG, which includes securities and futures exchanges, or with which the Exchange has in place a comprehensive surveillance sharing agreement. The Exchange states that FINRA, on behalf of the Exchange, will be able to access, as needed, trade information for certain fixed income securities held by the Fund reported to FINRA's TRACE.

The Exchange represents that the Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. In support of this proposal, the Exchange has made representations, including:

(1) The Shares will be subject to Rule 5735, which sets forth the initial and continued listing criteria applicable to Managed Fund Shares.

(2) The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.

(3) Trading in the Shares will be subject to the existing trading surveillances, administered by both Nasdaq and also FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws, and that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws.

(4) Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (a) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (b) Nasdaq Rule 2111A, which imposes suitability obligations on Nasdaq members with respect to recommending transactions in the Shares to customers; (c) how and by whom information regarding the Intraday Indicative Value and the Disclosed Portfolio is disseminated; (d) the risks involved in trading the Shares during the Pre-Market and Post-Market Sessions when an updated Intraday Indicative Value will not be calculated

or publicly disseminated; (e) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (f) trading information.

(5) For initial and continued listing, the Fund and the Subsidiary must be in compliance with Rule 10A-3 under the Act.³⁵

(6) The Fund's investments will be consistent with its respective investment objective. While the Fund and the Subsidiary may invest in inverse commodity-linked instruments, the Fund and the Subsidiary will not invest in leveraged or inverse leveraged (e.g., 2X or -3X) commodity-linked instruments.

(7) The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment), including securities deemed illiquid by the Adviser, in accordance with Commission guidance.

(8) Not more than 10% of the weight (to be calculated as the value of the contract divided by the total absolute notional value of the Subsidiary's futures contracts) of the futures contracts held by the Subsidiary in the aggregate shall consist of instruments whose principal trading market is not a member of ISG or is a market with which the Exchange does not have a comprehensive surveillance sharing agreement.

(9) All commodity-linked instruments in which the Subsidiary invests will be traded on ISG member markets. Commodity-linked instruments include: (a) Exchange-traded funds ("ETFs") that provide exposure to commodities as would be listed under Nasdaq Rules 5705 and 5735; and (b) pooled investment vehicles that invest primarily in commodities and commodity-linked instruments as would be listed under Nasdaq Rules 5710 and 5711(b), (d), (f), (g), (h), (i), and (j).

(10) The Fund and the Subsidiary will not invest in options contracts, swaps, or forward investments. In addition, the Fund will not invest directly in Commodities.

(11) A minimum of 100,000 Shares will be outstanding at the commencement of trading on the Exchange. This approval order is based on all of the Exchange's representations, including those set forth above and in the Notice, and the Exchange's description of the Fund.

³⁵ See 17 CFR 240.10A-3.

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 1 thereto, is consistent with Section 6(b)(5) of the Act³⁶ and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,³⁷ that the proposed rule change (SR-NASDAQ-2014-059), as modified by Amendment No. 1 thereto, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁸

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014-18533 Filed 8-5-14; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-72730; File No. SR-BYX-2014-013]

Self-Regulatory Organizations; BATS Y-Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 11.24(a)(2) to Include Riskless Principal Orders To the Types of Orders that May Qualify as Retail Orders under the Retail Price Improvement Program

July 31, 2014.

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 July 24, 2014, BATS Y-Exchange, Inc. (the "Exchange" or "BYX") 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 Exchange. The Exchange has designated this proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b-4(f)(6)(iii) thereunder,⁴ which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend Exchange Rule 11.24(a)(2) to include riskless principal orders to the types of orders that may qualify as Retail Orders under the Exchange's Retail Price Improvement Program (the "RPI Program"). The Exchange has designated this proposal as non-controversial and provided the Commission with the notice required by Rule 19b-4(f)(6)(iii) under the Act.⁵

The text of the proposed rule change is available at the Exchange's Web site at <http://www.bats trading.com>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rule 11.24(a)(2) to include riskless principal orders to the types of orders that may qualify as Retail Orders under the Exchange's RPI Program.⁶ The Exchange established the RPI Program in an attempt to attract retail order flow to the Exchange by potentially providing price improvement to such order flow.⁷ Under the RPI Program, all Exchange Users⁸ are permitted

members to submit Retail Price Improvement Orders ("RPI Orders")⁹ which are designed to provide potential price improvement for Retail Orders in the form of non-displayed interest that is better than the national best bid that is a Protected Quotation ("Protected NBB") or the national best offer that is a Protected Quotation ("Protected NBO", and together with the Protected NBB, the "Protected NBBO").¹⁰ The Exchange believes that the RPI Program promotes competition for retail order flow by allowing Exchange Users to submit RPI Orders to interact with Retail Orders.

Exchange Rule 11.24(a)(2) currently defines a Retail Order as, "an agency order 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 the market and the order does not originate from a trading algorithm or any other computerized methodology." The Exchange believes that its definition of a Retail Order is unnecessarily restrictive compared to that of other exchanges because it does not include "riskless principal orders" in its definition.¹¹ The Exchange believes that its comparatively narrow definition may create confusion among the Exchange's Members,¹² preventing

⁹ A "Retail Price Improvement Order" is defined in Rule 11.24(a)(3) as an order that consists of non-displayed interest on the Exchange that is priced better than the Protected NBB or Protected NBO by at least \$0.001 and that is identified as such. See Rule 11.24(a)(3).

¹⁰ The term Protected Quotation is defined in BYX Rule 1.5(t) and has the same meaning as is set forth in Regulation NMS Rule 600(b)(58). The terms Protected NBB and Protected NBO are defined in BYX Rule 1.5(s). The Protected NBB is the best-priced protected bid and the Protected NBO is the best-priced protected offer. Generally, the Protected NBB and Protected NBO and the national best bid ("NBB") and national best offer ("NBO", together with the NBB, the "NBBO") will be the same. However, a market center is not required to route to the NBB or NBO if that market center is subject to an exception under Regulation NMS Rule 611(b)(1) or if such NBB or NBO is otherwise not available for an automatic execution. In such case, the Protected NBB or Protected NBO would be the best-priced protected bid or offer to which a market center must route interest pursuant to Regulation NMS Rule 611.

¹¹ The Exchange notes that other market centers include "riskless principal orders" as part of their definitions of "Retail Orders." See, e.g., Securities Exchange Act Release No. 68937 (February 15, 2013), 78 FR 12397 (February 22, 2013) (SR-NASDAQ-2012-129); Securities Exchange Act Release No. 69103 (March 11, 2013), 78 FR 16547 (March 15, 2013) (SR-NYSE-2013-20); Securities Exchange Act Release No. 69104 (March 11, 2013), 78 FR 16556 (March 15, 2013) (SR-NYSEMKT-2013-22); and Securities Exchange Act Release No. 69378 (April 15, 2013), 78 FR 23617 (April 19, 2013) (SR-EDGX-2013-13).

¹² The term "Member" is defined as "any registered broker or dealer that has been admitted

Continued

³⁶ 15 U.S.C. 78f(b)(5).

³⁷ 15 U.S.C. 78s(b)(2).

³⁸ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b-4(f)(6)(iii).

⁵ 17 CFR 240.19b-4(f)(6)(iii).

⁶ The Exchange notes that in order to qualify as a Retail Order, a riskless principal order must satisfy the criteria set forth in FINRA Rule 5320.03.

⁷ See Securities Exchange Act Release No. 68303 (November 27, 2012), 77 FR 71652 (December 3, 2012) ("RPI Approval Order") (SR-BYX-2012-019). See also Securities Exchange Act Release No. 71249 (January 7, 2014), 79 FR 2229 (January 13, 2014) (SR-BYX-2014-001) (Notice of Filing and Immediate Effectiveness extending pilot period until January 31, 2015).

⁸ A "User" is defined "as any member or sponsored participant of the Exchange who is authorized to obtain access to the System." BYX Rule 1.5(cc).

Members from participating in the RPI Program. In addition, the Exchange believes that the restrictiveness of the Exchange's definition may inadvertently put the Exchange at a competitive disadvantage in relation to other exchanges that provide a less restrictive definition of a Retail Order.

Accordingly, the Exchange proposes to amend the definition of a Retail Order in under Rule 11.24(a)(2) to include riskless principal orders to the types of orders that may qualify as Retail Orders.¹³ The Exchange proposes to amend Rule 11.24(a)(2) to define a Retail Order as, "an agency order or riskless principal 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" (emphasis added).¹⁴ The Exchange believes that, for purposes of determining whether an order should qualify as a Retail Order, there is no substantive difference between an agency order and a riskless principal order that meets the requirements of FINRA Rule 5320.03. A riskless principal transaction is a transaction in which a Member, after having received an order to buy (sell) a security, purchases (sells) the security as principal and, contemporaneously, satisfies the original order by selling (buying) as principal at the same price. Generally, a riskless principal transaction involves two orders, the execution of one being dependent upon the receipt or execution of the other; thus, there is no "risk" in the interdependent transactions when completed. Unlike a riskless principal transaction, an agency order is entered directly in the System¹⁵ by a Member

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. Membership may be granted to a sole proprietor, partnership, corporation, limited liability company or other organization which is a registered broker or dealer pursuant to Section 15 of the Act, and which has been approved by the Exchange." See Exchange Rule 1.5(n).

¹³ The Exchange notes that in order to qualify as a Retail Order, a riskless principal order must satisfy the criteria set forth in FINRA Rule 5320.03.

¹⁴ The Exchange notes that it will amend its attestation form for Members designating Retail Orders to conform to these new requirements. The definition of Retail Order under Rule 11.24(a)(2) will continue to state that a Retail Order is an Immediate or Cancel ("IOC") Order and shall operate in accordance with paragraph (f) of Rule 11.24 and that a Retail Order may be an odd lot, round lot, or mixed lot.

¹⁵ The term "System" is defined as "the electronic communications and trading facility

on behalf of a customer. Ultimately, however, the results of a riskless principal transaction and an agency order are the same: the customer receives an execution while the involved Member acts as an intermediary to effect the transaction.¹⁶

The Exchange believes that the requirement that the entry of such riskless principal orders satisfy FINRA Rule 5320.03 provides sufficient protection against Members submitting orders for their own account to the Exchange. A Member entering a riskless principal transaction will have to, contemporaneously with the execution of the customer's order, submit a report identifying the trade as riskless principal to FINRA. Additionally, the Member will need to have written policies and procedures to ensure that riskless principal transactions comply with applicable FINRA rules. The policies and procedures, at a minimum, must require that the customer order be received prior to the offsetting principal transaction, and that the offsetting principal transaction is at the same price as the customer order exclusive of any markup or markdown, commission equivalent, or other fee, and is allocated to a riskless principal or customer account in a consistent manner and within 60 seconds of execution. Additionally, the Member must have supervisory systems in place that produce records that enable the Member and FINRA to reconstruct accurately, readily, and in a time-sequenced manner all Retail Orders that are entered on a riskless principal basis.

The Exchange believes that the Member must also ensure that non-Retail Orders from customers are not included with the Retail Orders as part of a riskless principal transaction. The above requirements ensure that despite the procedural differences between the execution of a riskless principal transaction and an agency order, the only difference will be the procedure in which the transactions are effected and not the result.

The Exchange further believes that clarifying that riskless principal orders that meet the requirements of FINRA Rule 5320.03 are able to be submitted as Retail Orders on the same basis as agency orders will enable Members, and in turn, their retail customers, to benefit from the price improvement

designated by the Board through which securities orders of Users are consolidated for ranking, execution and, when applicable, routing away." Exchange Rule 1.5(aa).

¹⁶ A principal transaction differs from both a riskless principal transaction and an agency order in that it is an order for the principal account of the entering Member.

opportunities available under the Exchange's RPI Program.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act¹⁷ in general, and furthers the objectives of Section 6(b)(5) of the Act¹⁸ 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 the proposed rule change promotes just and equitable principles of trade because it will ensure that riskless principal orders that meet the requirements of FINRA Rule 5320.03 will have the same opportunity to be submitted as Retail Orders as agency orders. As discussed above, there is no functional distinction for purposes of Retail Orders between an order entered by a Member on an agency basis and one entered on a riskless principal basis. The Exchange believes that the proposed change would tend to reduce any potential discrimination between similarly situated customers or brokers by ensuring that the ability of retail customers to benefit from the use of Retail Orders and price improvement opportunities available under the Exchange's RPI Program does not depend on a distinction in capacity that is not meaningful for purposes of submitting Retail Orders. As a result of the change, a retail customer would be able to in the RPI Program utilizing Retail Orders without regards to whether the Member enters the order on a riskless principal or agency basis.

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 clarify that riskless principal orders that meet the requirements of FINRA Rule 5320.03 are eligible to be submitted as Retail Orders on the same basis as agency orders. By allowing all orders that are functionally equivalent to agency orders to be submitted as Retail Orders, the proposed change would potentially stimulate further competition for retail order flow because it is similar to the definition of

¹⁷ 15 U.S.C. 78f(b).

¹⁸ 15 U.S.C. 78f(b)(5).

retail order available on other exchanges.¹⁹

The Exchange believes that the proposed change would protect investors and the public interest by expanding the access of Members to the RPI Program offered by the Exchange as well as the access of the public to an exchange sponsored alternative to broker-operated internalization venues. In this regard, the Exchange believes that maintaining or increasing the proportion of Retail Orders in exchange-listed securities that are executed on a registered national securities exchange (rather than relying on certain available off-exchange execution methods) would contribute to investors' confidence in the fairness of their transactions and would benefit all investors by deepening the Exchange's liquidity pool, supporting the quality of price discovery, promoting market transparency and improving investor protection.

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 RPI Program, will increase the level of competition around retail executions such that retail investors would receive better prices than they currently do on the Exchange and potentially through bilateral internalization arrangements. The Exchange believes that the transparency and competitiveness of operating a program such as the RPI Program on an exchange market would result in better prices for retail investors and benefits retail investors by expanding the capabilities of the Exchange to encompass practices currently allowed on non-exchange venues. In addition, by allowing all orders that are functionally equivalent to agency orders to be submitted as Retail Orders, the proposed change would potentially stimulate further competition for retail order flow because it is similar to the definition of retail order available on other exchanges.²⁰

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

The Exchange has neither solicited nor received written comments on 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) of the Act²¹ and Rule 19b-4(f)(6)²² thereunder. Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act²³ and subparagraph (f)(6) of Rule 19b-4 thereunder.²⁴

A proposed rule change filed under Rule 19b-4(f)(6) normally does not become operative for 30 days after the date of filing.²⁵ However, Rule 19b-4(f)(6)(iii) permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest.²⁶ The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because such waiver would allow riskless principal orders meeting the requirements of FINRA Rule 5320.03 to immediately qualify as retail orders, and thereby allow more Exchange members to benefit from the price improvement opportunities available under the Exchange's RPI Program. The Exchange also believes that waiving the 30-day operative delay would enable the Exchange to remain competitive with other market centers by providing an additional choice to its members as to where they send retail orders on a

riskless principal basis. The Exchange notes that several other exchanges presently include riskless principal orders within their definition of a retail order.²⁷ The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.²⁸

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act.²⁹ If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.³⁰

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-BYX-2014-013 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-BYX-2014-013. 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

²¹ 15 U.S.C. 78s(b)(3)(A).

²² 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.

²³ 15 U.S.C. 78s(b)(3)(A).

²⁴ 17 CFR 240.19b-4(f)(6).

²⁵ 17 CFR 240.19b-4(f)(6)(iii).

²⁶ *Id.*

²⁷ See, e.g., Securities Exchange Act Release Nos. 68937 (February 15, 2013), 78 FR 12397 (February 22, 2013) (SR-NASDAQ-2012-129); 69103 (March 11, 2013), 78 FR 16547 (March 15, 2013) (SR-NYSE-2013-20); 69104 (March 11, 2013), 78 FR 16556 (March 15, 2013) (SR-NYSEMKT-2013-22); and 69378 (April 15, 2013), 78 FR 23617 (April 19, 2013) (SR-EDGX-2013-13).

²⁸ 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).

²⁹ 15 U.S.C. 78s(b)(3)(C).

³⁰ *Id.*

¹⁹ See Footnote 4 of the EDGX Exchange, Inc. ("EDGX") fee schedule available at <http://www.directedge.com/Trading/EDGXFeeSchedule.aspx> (last visited July 16, 2014); NASDAQ Stock Market LLC Rule 4780(a)(2); New York Stock Exchange, Inc. Rule 107C(a)(3) and NYSE MKT LLC Rule 107C(a)(3).

²⁰ *Id.*

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-BYX-2014-013, and should be submitted on or before August 27, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³¹

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014-18534 Filed 8-5-14; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-72736; File No. SR-NASDAQ-2014-075]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness To Correct Language in the Text of Rule 4753

August 1, 2014.

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 July 22, 2014, 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 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 the Substance of the Proposed Rule Change

The Exchange proposes to amend NASDAQ Rule 4753 to correct imprecise language in the rule text. The text of the proposed rule change is available at <http://nasdaq.cchwallstreet.com/>, at the Exchange'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, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

NASDAQ is amending the language of Rule 4753 to correct imprecise language with respect to imbalance information disseminated prior to the execution of the NASDAQ Halt Cross (the "Halt Cross" or "Cross"). The NASDAQ Halt Cross is designed to provide for an orderly, single-priced opening of securities subject to an intraday halt, including securities that are the subject of an initial public offering ("IPO"). Prior to the Cross execution, market participants enter quotes and orders eligible for participation in the Cross, and NASDAQ disseminates certain information regarding buying and selling interest entered and the indicative execution price. The information disseminated by NASDAQ is referred to in Rule 4753 as the "Order Imbalance Indicator", but is sometime also referred to by NASDAQ and by market participants as the "Net Order Imbalance Indicator" or "NOII".

At the time when the security is released for trading, the Halt Cross will occur at the price that maximizes the number of shares of trading interest eligible for participation in the Cross³ to

be executed. If there is more than one such price, the Cross will occur at the price that minimizes any Imbalance, which is defined in the rule as "the number of shares of Eligible Interest that may not be matched with other order shares at a particular price at any given time."⁴ The NOII is disseminated every five seconds during a designated period prior to the completion of the Halt Cross, in order to provide market participants with information regarding the possible price and volume of the Cross. The information includes the Current Reference Price, which is the price at which the Cross would occur if it executed at the time of the NOII's dissemination, and the number of shares of Eligible Interest that would be paired at that price. Rule 4753 also provides that the NOII includes "the size of any Imbalance" and "the buy/sell direction of any Imbalance", as well as "an indicator for 'market buy' or 'market sell'." "[i]f marketable buy (sell) shares would remain unexecuted above (below) [the Current Reference Price]".

While the NOII does provide certain information regarding shares that might not be executed in the Cross, the information provided is not precisely described by the defined term "Imbalance". It appears, however, that the original drafter of the rule concluded that because the NOII does include certain information that might be generally understood to concern imbalances, the defined term used for determining the Cross price would also serve to describe the NOII. This conclusion may have also been influenced by the text of Rules 4752 and 4754, which describe the NASDAQ Opening Cross and the NASDAQ Closing Cross and which accurately use a similar defined term to describe information provided by the NOII for those crosses. However, the NOII for the Halt Cross provides information about shares that might not be executed in the Cross only when the 'market buy' or 'market sell' indicator described in current Rule 4753(a)(2)(E)(iii) is being disseminated, in which case the number of shares of Eligible Interest entered through market orders that would not be executed in the Cross would be disseminated.⁵ NASDAQ believes that the dissemination of imbalance

designated with a time-in-force of SIOC, SDAY, SGTC, MIOC, MDAY, MGTC, SHEX or GTMC. These respective times-in-force are defined in Rule 4751.

⁴ Additional provisions of Rule 4753, not pertinent to this proposed rule change, are used to determine the price in the event that there is more than one price that minimizes any Imbalance.

⁵ The information disseminated does not include marketable limit orders.

³¹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 U.S.C. 240.19b-4.

³ "Eligible Interest" is defined as any quotation or any order that may be entered into the system and

information focused on unmatched market orders because the Cross cannot occur if not all market orders would be executed. Therefore, the information is designed to solicit offsetting liquidity that would allow the Cross to execute. NASDAQ further believes that the information currently provided through the NOII is well understood by market participants, and that as a result, a modification to the rule text to clarify it will not result in any confusion or alteration in expectations on the part of market participants.

To address this issue in a comprehensive manner, NASDAQ is proposing to adopt a new defined term—Market Order Imbalance—that will be defined as “the number of shares of Eligible Interest entered through market orders that would not be matched with other order shares at the time of the dissemination of an Order Imbalance Indicator.” NASDAQ is then proposing to amend current Rule 4753(a)(2)(C) and (D) to provide that the NOII includes the size and buy/sell direction of a Market Order Imbalance, rather than an Imbalance. Finally, NASDAQ proposes to delete Rule 4753(a)(2)(E)(iii), since it describes the buy/sell direction of a Market Order Imbalance and is therefore redundant.⁶

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b) of the Act⁷ in general, and furthers the objectives of Section 6(b)(5),⁸ in particular, in that it is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest. The proposal is consistent with these purposes because it will ensure that Rule 4753 clearly describes the information provided in the NOII for the Halt Cross.

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. Because the proposal is designed merely to ensure

that Rule 4753 clearly describes the information provided in the NOII for the Halt Cross, it does not affect competition in any respect.

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

Because the foregoing proposed rule change does not:

- (i) Significantly affect the protection of investors or the public interest;
- (ii) impose any significant burden on competition; and
- (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)⁹ of the Act and Rule 19b-4(f)(6)¹⁰ thereunder.

A proposed rule change filed under Rule 19b-4(f)(6) of the Act¹¹ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii) of the Act,¹² the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange believes that because the proposed rule change is designed solely to correct and clarify rule text, the public interest and protection of investors will be better served by immediately implementing the proposed rule change.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because waiver will clarify the rule immediately, which could prevent investor confusion with respect to the rule. The Commission hereby waives the 30-day operative delay and designates the proposed rule change to

be operative upon filing with the Commission.¹³

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule 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-NASDAQ-2014-075 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-2014-075. 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.,

¹³ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

⁶ NASDAQ is also proposing to eliminate current reserve subsection (c) of the rule, and to delete several obsolete references to the NASDAQ Imbalance Cross, which was otherwise deleted from the rulebook by Securities Exchange Act Release No. 67678 (August 16, 2012), 77 FR 50738 (August 22, 2012) (SR-NASDAQ-2012-094).

⁷ 15 U.S.C. 78f(b).

⁸ 15 U.S.C. 78f(b)(5).

⁹ 15 U.S.C. 78s(b)(3)(A).

¹⁰ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of the filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹¹ 17 CFR 240.19b-4(f)(6).

¹² 17 CFR 240.19b-4(f)(6)(iii).

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 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–NASDAQ–2014–075, and should be submitted on or before August 27, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁴

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–18582 Filed 8–5–14; 8:45 am]

BILLING CODE 8011–01–P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2014–0044]

Notice of Senior Executive Service Performance Review Board Membership

AGENCY: Social Security Administration.

ACTION: Notice of Senior Executive Service Performance Review Board Membership.

Title 5, U.S. Code, 4314(c)(4), requires that the appointment of Performance Review Board members be published in the **Federal Register** before service on said Board begins.

The following persons will serve on the Performance Review Board which oversees the evaluation of performance appraisals of Senior Executive Service members of the Social Security Administration:

Donna Calvert
Hyacinth Hinojosa
James Julian
Michael Kramer *
Lydia Marshall
Natalie Lu *
Royce Min
Rosemary Stricks *
David Thomas *
Amy Thompson
Laura Train
* New Member

Dated: July 29, 2014.

Reginald F. Wells,

Deputy Commissioner for Human Resources.

[FR Doc. 2014–18560 Filed 8–5–14; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2014–0028]

Agency Information Collection Activities: Request for Comments for the Renewal of a Previously Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that FHWA will submit the collection of information described below to the Office of Management and Budget (OMB) for review and comment. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on June 5, 2014. The PRA submission describes the nature of the information collection and its expected cost and burden.

DATES: Please submit comments by September 5, 2014.

ADDRESSES: You may submit comments identified by DOT Docket ID 2014–0028 by any of the following methods:

Web site: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ann Shemaka, 202–366–1575, Office of Bridge Technology, Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: National Bridge Inspection Program.

Background: This collection is necessary to meet legislative requirements of Title 23 United States Code section 144, and the Code of

Federal Regulations, 23 Highways Part 650, Subpart C—National Bridge Inspection Standards which require States, Federal Agencies, and Tribal Governments to: (1) Perform and report inventory data from routine inspections, fracture critical inspections, and underwater inspections on all highway bridges on public roads, and element level inspections on highway bridges on the National Highway System; (2) report costs associated with the replacement of structurally deficient bridges; and (3) follow up on critical findings. The bridge inspection and replacement cost information that is provided to the FHWA is on an annual basis. The critical findings information is periodically provided to the FHWA. The bridge information is used for multiple purposes, including: (1) The determination of the condition of the Nation's bridges which is included in a biennial report to Congress on the Status of the Nation's Bridges; (2) for a report to the Committee on Transportation and Infrastructure of the House of Representatives and the Committee on Environment and Public Works of the Senate on the Nation's bridge inventory; (3) the data source for executing various sections of the Federal-aid program which involve highway bridges; (4) the data source for assessing the bridge penalty provisions of Title 23 United States Code section 119; and (5) for strategic national defense needs.

Respondents: 52 State highway agencies including the District of Columbia and Puerto Rico, Federal Agencies, and Tribal Governments. The number of inspections per respondent varies in accordance with the National Bridge Inspection Standards.

Estimated Average Burden per Response: The estimated average burden for each bridge inspection is 8 hours. The estimated average burden for each element level inspection is 25 minutes. The estimated average burden for each cost collection report is 90 hours. The estimated average burden for follow up on critical findings is 40 hours.

Estimated Total Annual Burden Hours: The annual burden hours associated with this renewal is 2,490,118 hours. This estimated figure is based on 306,800 annual instances for routine, fracture critical, and underwater inspections multiplied by 8 hours (2,454,400 hours); plus 69,500 annual element inspections multiplied by 25 minutes (28,958 hours); plus 90 hours for each cost report multiplied by 52 reports (4,680 hours); plus 40 hours for follow up on critical findings multiplied by 52 respondents (2,080 hours) for a combined annual burden of 2,490,118 hours.

¹⁴ 17 CFR 200.30–3(a)(12).

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection of information is necessary for the U.S. DOT's performance, including whether the information will have practical utility; (2) the accuracy of the U.S. DOT's estimate of the burden of the proposed information collection; (3) ways to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued on: August 1, 2014.

Michael Howell,

Information Collection Officer.

[FR Doc. 2014-18655 Filed 8-5-14; 8:45 am]

BILLING CODE 4910-22-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA-2014-0030]

Agency Information Collection

Activities: Request for Comments for the Renewal of a Previously Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3521), this notice announces that FHWA will submit the collection of information described below to the Office of Management and Budget (OMB) for review and comment. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on June 5, 2014. The PRA submission describes the nature of the information collection and its expected cost and burden.

DATES: Please submit comments by September 5, 2014.

ADDRESSES: You may submit comments identified by DOT Docket ID 2014-0030 by any of the following methods:

Web site: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

Fax: 1-202-493-2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Craig Thor, Ph.D., Office of Safety Research and Development (HRDS), at (202) 493-3338, Turner-Fairbank Highway Research Center, Federal Highway Administration, 6300 Georgetown Pike, McLean VA 22101, between 7:00 a.m. and 4:30 p.m., Monday through Friday, except Federal Holidays.

SUPPLEMENTARY INFORMATION:

Title: Motorcycle Crash Causation Study.

OMB Control #: 2125-0619.

Background: In 2011, there were 4,612 motorcycle crash-related fatalities in the United States—more than twice the number of motorcycle rider fatalities that occurred in 1997. This increase contrasts with a 33% reduction in the number of fatalities in passenger cars and light trucks.¹ In response to this growing concern, the U.S. Congress passed legislation to fund a Federal Highway Administration (FHWA) research effort into the causes of motorcycle crashes in the United States. Congress has recognized this problem and directed the Department of Transportation to conduct research that will provide a better understanding of the causes of motorcycle crashes. Specifically, in Section 5511 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU) Public Law 109-59, Congress directed the Secretary of Transportation to provide grants to the Oklahoma Transportation Center (OTC) for the purpose of conducting a comprehensive, in-depth motorcycle crash causation study that employs the common international methodology for in-depth motorcycle crash investigation developed by the Organization for Economic Cooperation and Development (OECD).² The Secretary of Transportation delegated authority to FHWA for the Motorcycle Crash

Causation Grants under Section 5511 (71 FR 30831). This study began in June, 2012 and has been successful in completing the necessary data collection.

Proposed Data Acquisition Methodology

Use of Parallel and Complementary Procedures

The OECD describes two complementary procedures to be performed for acquiring the data needed to understand the causes of motorcycle crashes. The first of these is the traditional in-depth crash investigation that focuses on the sequence of events leading up to the crash, and on the motorcycle, rider, and environmental characteristics that may have been relevant to the crash. The second procedure, known as the case-control procedure, complements the first. It requires the acquisition of matched control data to allow for a determination of the extent to which rider characteristics and pre-crash factors observed in the crash vehicles are present in similarly-at-risk control vehicles.

Such a dual approach offers specific advantages to the understanding of crashes and the development of countermeasures. The in-depth study of the crash by itself allows for analysis of the events antecedent to the crash, some of which, if removed or altered, could result in a change in subsequent events that would have led to a non-crash, or reduced crash severity outcome. The main purpose of acquiring matched data is to allow for inferences to be made regarding risk factors for crash causes. A brief explanation is provided here so that those less familiar with case-control procedures will understand the advantage of acquiring controls. Consider a hypothetical situation where it is observed that the proportion of *older riders* involved in crashes who were unfamiliar with the roadway is the *same as* the proportion of matched (similarly-at-risk) older control motorcycle riders not involved in crashes. Conversely, the proportion of *younger riders* involved in crashes who were unfamiliar with the roadway is the *greater than* the proportion of matched younger control motorcycle riders not involved in crashes. These hypothetical findings would suggest that a lack of familiarity with the roadway poses a greater crash risk for younger riders than it does for older riders. Other risk factors for crashes (i.e. gender, riding experience, fatigue level) for motorcyclists may also be examined in this manner. If scaled interval

¹ NHTSA FARS encyclopedia: <http://www-fars.nhtsa.dot.gov/Main/index.aspx>.

² The OECD methodology may be obtained by sending a request to jtrc.contact@oecd.org.

measurements of risk factor levels are obtained (for example, the number of years of riding experience for both crash-involved and control riders), then it becomes possible to calculate functions showing how risk changes with changes in the variable of interest. Such risk functions are highly useful in the development of countermeasures.³

Issues Related to Sampling

Characteristics of the Crash Sample

To properly acquire in-depth crash data, it was necessary to find a location in the country that experiences the full range of motorcycle crash types that occur under a wide range of conditions and with a wide range of motorcycle rider characteristics. For this study, Orange County, California was selected as the data collection site. This location resembles a cross-section of motorcycle riding environments. There are both rural and urban regions; flat land and rolling hills; and daily commuters and leisure riders, therefore, the data collected from this region should reflect many of the causative factors that produce motorcycle crashes in these different riding environments. This location also allows for a sufficiently high frequency of motorcycle crashes to allow acquisition of the crash data in a reasonable amount of time. To date, this single location has proven to be sufficient to collect the required number of cases and controls.

It is not necessary that the crash types observed (or other composite indices or parameters of interest) be drawn from a nationally representative sample, because it is not the intent of FHWA to make projections of the national incidence of the causes of crashes involving motorcycles from this study. Rather, the focus will be on identifying the antecedents and risk factors associated with motorcycle crashes. If it is deemed necessary, FHWA and NHTSA may utilize their alternative databases that incorporate certain of the key variables that will be acquired in this study, and those databases could be used in conjunction with this study's data to make national estimates of population parameters of interest.⁴

³ Certainly other outcomes besides the one presented are possible, and other comparisons are of interest.

⁴ There is a lengthy precedent for studying crashes using case-control methods including the Grand Rapids study, (Borkenstein, R.F., Crowther, F.R., Shumate, R.P., Ziel, W.B. & Zylman, R. (1974). The Role of the Drinking Driver in Traffic Accidents (The Grand Rapids Study). Blutalkohol, 11, Supplement 1), and of course the Hurt study, (Hurt, H.H., Jr., Ouellet, J.V., and Thom, D.R. (1981). Motorcycle Accident Cause Factors and

In addition, the crash investigations will be conducted on-scene, and, when possible, while the involved operators and vehicles are still in place. This provides access to physical data that is less disturbed by rescue and clean up activities. It also facilitates the collection of interview data while memories are unaffected. This quick-response approach is most effective when a census of applicable crashes is selected for inclusion.

Characteristics of the Control Sample

While the occurrence of a crash involving a motorcycle in the study site is sufficient for it to be selected into the study, selecting the similarly-at-risk controls requires a different approach. The OECD recommends several options for acquiring matched controls including interviewing motorcyclists who may be filling up at nearby gas stations, taking videos of motorcyclists who pass the crash scenes, and interviewing motorcyclists at the location of the crash location at the same time of day, same day of week, and same direction of travel. The first of these methods suffers from the shortcoming that a rider or motorist filling his fuel tank is not presented with the same risks, in the same setting, as is the crash-involved rider and motorist. Passenger-vehicle motorists and motorcyclists need to be sampled at the location of the crash on the same day of the week, at the same hour, and from the same travel direction.

Using the second method mentioned above, acquiring the risk sample by taking video at the crash scene provides a similarly-at-risk pool and it also allows for many controls to be acquired at low cost. Its chief disadvantage is that it does not allow capture of some of the key risk factors for crashes (e.g., fatigue), while others (e.g., age) may be very difficult to capture. Therefore, this method is not sufficient to support the scope of the current effort.

The final method, the voluntary safety research interview, involves setting up a safety zone at or near the crash location, one week later at the same time of day, and asking those motorcyclists who pass through to volunteer in a study. With this method, Certificates of Confidentiality are presented to each interviewed driver and rider and immunity is provided. The main advantage of this method is that the key variables that are thought to affect relative crash risk can be acquired from riders who are truly similarly-at-risk.

This is the method used in the current effort.

Information Proposed for Collection

The data collection protocol includes the following number of variables for each aspect of the investigation:

Data collection form	Number of questions
Administrative log	43
Crash Form	22
Motorcycle Rider Form	105
Motorcycle Passenger	65
Motorcycle Mechanical	91
Motorcycle Dynamics	43
Environment Form	51
Helmet Form	77
Other Vehicle Form	26
Injury Form	160

Note that multiple copies of various data forms will be completed as the data on each crash-involved vehicle and person and each control vehicle and person are acquired. This increases the number of variables above the sum of what is presented above. There are also diagrams and photographs that are essential elements of each investigation that are entered into the database. Up to 1,600 data elements may be collected for each case, including the control rider data.

Estimated Burden Hours for Information Collection

Frequency: Annually.

Respondents: This study will be based on all crashes occurring within the sampling area. This burden estimate is based on the distribution of crash types seen in the study to date. The plan calls for data to be captured from up to 1,200 crashes with motorcycle involvement, and for all surviving crash-involved riders and drivers to be interviewed. Two control riders will be interviewed for each crash-involved motorcyclist. Passengers accompanying crash-involved riders and passenger-vehicle drivers will also be interviewed. The following table shows the sampling plan and estimated number of interviews assuming 1,200 crashes are investigated.⁵

Maximum total crashes to be investigated is 1,200.

⁵ The final crash sample size will depend on the rate at which crashes can be acquired in the selected site(s) and other matters related to logistics and the final budget.

Crash Interviews:

Single vehicle motorcycle crashes	252
Multi-vehicle (2-vehicle) motorcycle crashes (840*2)	1,680
Passenger interviews motorcycle (.07* 252 + .07*1680)	136
Passenger interviews cars (.19*235)	319
Total Crash Interviews	2,387
Control interviews:	
Controls for single vehicle motorcycle crashes (2*252)	504
Controls for multi-vehicle motorcycle crashes (1*840 + 1*840)	1,680
Passenger Interviews	0
Total Control Interviews	2,184
Grand Total Crash plus Control Interviews	4,571

Estimated Average Burden per Interviewee: Crash interviews are estimated to require about 30 minutes per individual interviewed. To the extent possible, crash interviews will be collected at the scene, although it is likely that some follow-ups will be needed to get completed interviews from crash involved individuals. Control individuals' interviews will be completed in a single session and are expected to require about 15 minutes per individual.

Estimated Total Annual Burden Hours: Burden hours estimates are based on the total of 2,387 crash interviews to be conducted at an average length of 30 minutes each and 2,184 control interviews to be conducted at an average length of 15 minutes each for a total one-time burden on the public of 1,770 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued On: August 1, 2014.

Michael Howell,

Information Collection Officer.

[FR Doc. 2014-18656 Filed 8-5-14; 8:45 am]

BILLING CODE 4910-22-P

DEPARTMENT OF TRANSPORTATION**Federal Motor Carrier Safety Administration**

[FMCSA-2014-0034]

Hours of Service of Drivers: Payne and Dolan, Inc.; Zenith Tech, Inc.; and Northeast Asphalt, Inc.; Application for Exemption

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA announces that it has received an application from Payne and Dolan, Inc.; Zenith Tech, Inc.; and Northeast Asphalt, Inc. for an exemption from the 30-minute rest break provision of the Agency's hours-of-service (HOS) regulations for commercial motor vehicle (CMV) drivers. The requested exemption would apply to CMV drivers of these three companies involved in the transport, placement and movement of materials and equipment needed in the day-to-day operation of road, bridge and parking lot construction and maintenance. These companies believe that compliance with the 30-minute rest break rule is extremely difficult due to several variables associated with the nature of their operations and work scheduling (e.g., work zone time, delivery and repair schedules). FMCSA requests public comment on these companies application for exemption.

DATES: Comments must be received on or before September 5, 2014.

ADDRESSES: You may submit comments identified by Federal Docket Management System Number FMCSA-2014-0034 by any of the following methods:

- **Federal eRulemaking Portal:** www.regulations.gov. Follow the online instructions for submitting comments.
- **Fax:** 1-202-493-2251.
- **Mail:** Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building,

Ground Floor, Room W12-140, Washington, DC 20590-0001.

- **Hand Delivery or Courier:** West Building, Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the Agency name and docket number. For detailed instructions on submitting comments and additional information on the exemption process, see the *Public Participation* heading below. Note that all comments received will be posted without change to www.regulations.gov, including any personal information provided. Please see the *Privacy Act* heading below.

Docket: For access to the docket to read background documents or comments received, go to www.regulations.gov, and follow the online instructions for accessing the dockets, or go to the street address listed above.

Privacy Act: Anyone can search the electronic form of 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 a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Public Participation: The Federal eRulemaking Portal is available 24 hours each day, 365 days each year. You can get electronic submission and retrieval help and guidelines under the "help" section of the Federal eRulemaking Portal Web site. If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard, or print the acknowledgement page that appears after submitting comments online. Comments received after the comment closing date will be included in the docket, and we will consider late comments to the extent practicable.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Clemente, FMCSA Driver and

Carrier Operations Division; Office of Bus and Truck Standards and Operations; Telephone: 202-366-4325. Email: MCPSD@dot.gov.

SUPPLEMENTARY INFORMATION:

Background

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain parts of the Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

Request for Exemption

On December 27, 2011 (76 FR 81133), FMCSA published a final rule amending its hours-of-service (HOS) regulations for property-carrying CMV drivers. The final rule adopted several changes to the HOS rules, including a new provision requiring drivers to take a rest break during the work day under certain circumstances. Drivers may now drive a CMV only if 8 hours or less have passed since the end of the driver's last off-duty or sleeper-berth period of at least 30 minutes. FMCSA did not specify when drivers must take the 30-minute break, but the rule requires that they wait no longer than 8 hours after the last off-duty or sleeper-berth period of that length or longer to take the break. Drivers who already take shorter breaks during the work day could comply with the rule by taking one of the shorter breaks and extending it to 30 minutes. This requirement took effect on July 1, 2013.

Payne and Dolan, Inc. Zenith Tech, Inc., and Northeast Asphalt, Inc. seek an

exemption from the 30-minute rest break provision in 49 CFR 395.3(a)(3)(ii), which would apply to these companies and their CMV drivers operating pavement repair and maintenance trucks. These companies currently operate roughly 1,000 trucks, driven by approximately 1,300 drivers in interstate commerce. According to these companies, compliance with the new 30-minute break rule is problematic, burdensome, and adversely impacts the effectiveness of the companies' delivery of material and equipment. Approximately 95 percent of their drivers spend less than 15 percent of their on-duty time actually driving a CMV—roughly only 2 hours per day—with the other 85 percent of the time spent on the job site performing their associated duties. Drivers pick up their equipment at a designated storage site and deliver it to the work site and unload on a daily basis, and the next time they are required to operate the CMV is to load and return the equipment to the storage yard at the end of the duty shift. Most Federal, State and municipal jobs give the contractor a finite amount of time to have the roads closed and perform the needed repairs—usually from 9:00 p.m. to 5:00 a.m. According to these three companies, with the requirement for these drivers to take the mandatory 30-minute break, the work zone time is shortened by one half hour, thus extending the length of time required to complete the scheduled repairs. They agree that they need the flexibility to deliver equipment and materials when the job and circumstances dictate the need, as these road repairs can't always be scheduled for 9:00 a.m. to 5:00 p.m. They further add that drivers in their industry segment are not subject to the fatigue-inducing work conditions that other CMV operators are.

Payne and Dolan, Inc. Zenith Tech, Inc. and Northeast Asphalt, Inc. state that materials delivered to an active job site have a short life span—the temperature of asphalt needs to be maintained—and should be considered a perishable product. Once the ingredients of the material have been mixed (or batched) there is a short “window” before the temperature drops to a point that it is no longer usable. An incident such as this costs thousands of dollars to rectify and could potentially cause a violation of a delivery contract. Once a delivery is started it must be completed, and all steps possible must be taken to ensure that a load of material reaches its destination on time and without disruption. An uninterrupted delivery is also necessary in case a

driver is made to wait a long period of time on a construction site before unloading—a common “real world” scenario according to the applicants for exemption. Adding a mandatory 30-minute break to this process risks the integrity of the industry's delivered product.

These companies believe the requested exemption would achieve the same level of safety as the 30-minute rest break because their drivers routinely receive numerous 10-, 15-, and 20-minute breaks throughout the work day, and it is not uncommon for their drivers to take breaks of up to 2 hours resulting from weather or unforeseen construction delays. They further claim that these frequent breaks work to keep the drivers awake and alert throughout the course of their duty period. One additional 30-minute break—as is now required by the FMCSRs—would not add an additional level of safety for their operation. The applicants state that the construction industry ensures drivers are as safe as possible and continue to use practices that emphasize safety. This attention to safety is achieved through mandating rigorous training for all truck drivers, daily, weekly, quarterly and annual safety checks, and self-imposed random safety audits. A copy of their exemption application is available for review in the docket for this notice.

Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315(b)(4), FMCSA requests public comment on this application for an exemption from one provision of the driver's HOS regulations in 49 CFR part 395. The Agency will consider all comments received by close of business on September 5, 2014. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will consider to the extent practicable comments received in the public docket after the closing date of the comment period.

Issued on: July 29, 2014.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2014-18646 Filed 8-5-14; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION**Federal Motor Carrier Safety Administration****[Docket No. FMCSA–2014–0009]****Qualification of Drivers; Exemption Applications; Vision****AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.**ACTION:** Notice of denials.

SUMMARY: FMCSA announces its denial of 128 applications from individuals who requested an exemption from the Federal vision standard applicable to interstate truck and bus drivers and the reasons for the denials. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemptions does not provide a level of safety that will be equivalent to, or greater than, the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

FOR FURTHER INFORMATION CONTACT:

Elaine M. Papp, Chief, Medical Programs Division, 202–366–4001, U.S. Department of Transportation, FMCSA, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:**Background**

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal vision standard for a renewable 2-year period if it finds “such an exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such an exemption.” The procedures for requesting an exemption are set forth in 49 CFR part 381.

Accordingly, FMCSA evaluated 128 individual exemption requests on their merit and made a determination that these applicants do not satisfy the criteria eligibility or meet the terms and conditions of the Federal exemption program. Each applicant has, prior to this notice, received a letter of final disposition on the exemption request. Those decision letters fully outlined the basis for the denial and constitute final Agency action. The list published in this notice summarizes the Agency’s recent denials as required under 49

U.S.C. 31315(b)(4) by periodically publishing names and reasons for denial.

The following applicant, Brian K. Coffman, did not have sufficient driving experience over the past 3 years under normal highway operating conditions.

The following 15 applicants had no experience operating a CMV:

Bryant L. Balkcom, Augustus H. Brooks, Francis E. Cannon, Isaac Cuautle, Robert Eggleston, Aaron Findley, Gregory J. Hyer, William D. Issacs, David M. Krause, Steven L. Lane, Nicholas A. Lupo, Arthur E. L. Marcotte, Michael McPartland, Randall T. Petersheim, Vincent J. Townsend

The following 31 applicants did not have 3 years of experience driving a CMV on public highways with their vision deficiencies:

Roy N. Aeschliman, Kwabena Apenteng, Wesley A. Barb, Carl Burks, Corey J. Colombo, Gary D. Crauthers, Demarcus Davis, Eric S. Dillon, Glenn D. Ferrell, David L. Fleming, Michael A. Greer, Carey G. Holland, James J. Kunkel, Edward O. Lemke, Brandon J. Michalko, Kenneth E. Morris, Sr., Moises Perez, Dale V. Petersen, Bryan W. Potratz, Jonathan A. Ramsey, Sr., Parker R. Roan, Jeff Saylor, Gary S. Seniuk, Robert Simpson, Peter G. Svoboda, Steve Szabo, Jason Watson, Donald J. Wilson, James W. Wise, Jr., Willie A. Young, Jr., Abdulkadir M. Yusuf.

The following 12 applicants did not have 3 years of recent experience driving a CMV with the vision deficiency:

Zach Afsher, Walter Benefield, Arthur Doult, Bill A. Drake, Stanfield L. Hunter, John Lucas, Rick Lunceford, Eric K. McCall, Ricky A. Schott, Roy Taylor, C. Pao, Thao, Curtis Townsend

The following 2 applicants did not have sufficient driving experience during the past 3 years under normal highway operating conditions:

Jason Muhammad, Otis Wright.

The following 4 applicants had their commercial driver’s license suspended during the 3-year review period for moving violations. Applicants do not qualify for an exemption with a suspension during the 3-year period:

Jay F. Brooks, Scott D. Goalder, Tony Gregoire, Steven R. Maddox.

The following applicant, Thomas D. Lane, contributed to an accident in which the applicant was operating a commercial motor vehicle.

The following 2 applicants were unable to obtain a statement from an optometrist or ophthalmologist stating that he was able to operate a commercial vehicle from a vision standpoint:

Steven E. Bumbrey, Robert Davis

The following 15 applicants were denied for miscellaneous/multiple reasons:

Lucas J. Brickner, Barry Bunker, Carol D. Cuthbertson, Robert L. Dinkins, Charles O. Drummond, David L. Gillion, Dennis E. Groothuis, Jose Guzman, Joshua A. Hernandez, Mehrim Hodzic, Robert P. Kelly, Rick P. Moreno, Timothy Smith, John P. Trebesch, Richard A. Wheeler

The following 21 applicants met the current federal vision standards. Exemptions are not required for applicants who meet the current regulations for vision:

Jorge E. Aldana, Don Amundsen, Warren M. Blakeney, Nathan Boehm, Alexander W. Bryant, James C. Honeycutt, Kerry Kersey, Rommie L. Knight, Rennard Lake, Manual S. Marquez, Jimmy C. Moore, Jr., Vasyly Myniv, Ronald L. Olberding, Juan A. Perez, Kent E. Riegel, Harry L. Ross, Donnie M. Russell, Kenny R. Taylor, David M. Terry, Timothy W. Trusty, Henry L. Washington, Jr.

The following 19 applicants were denied because they will not be driving interstate, interstate commerce, or not required to carry a DOT medical card:

Marco A. Alvarez, Tomas Benavidez, Jr., Marlin G. Burley, Jr., Jerome Carbaugh, Gareth T. Edwards, Richard T. Elijah, John A. Frymark, Marvin F. Guess, Robert Howell, Jr., Richard S. Huzzard, Vance L. Johnson, Augusto F. Nunez, Juan G. Padilla, Donald Reeves, Christopher M. Reynolds, Randall W. Schroeder, Martin Skovish, Sr., Terrence M. Thomas, Brian Weiner

Finally, the following 5 applicants perform transportation for the federal government, state, or any political subdivision of the state.

Johann Finley, Jeffery O. Galtney, Jimmy D. Renfroe, William C. Riddick, Timothy A. Wright

Issued on: July 29, 2014.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2014–18648 Filed 8–5–14; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION**Federal Motor Carrier Safety Administration**

[Docket No. FMCSA–1999–6480; FMCSA–2002–12294; FMCSA–2006–24015; FMCSA–2007–0071; FMCSA–2008–0021; FMCSA–2008–0106; FMCSA–2010–0114; FMCSA–2012–0161]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 15 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemption renewals will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

DATES: This decision is effective September 9, 2014. Comments must be received on or before September 5, 2014.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) numbers: Docket No. [Docket No. FMCSA–1999–6480; FMCSA–2002–12294; FMCSA–2006–24015; FMCSA–2007–0071; FMCSA–2008–0021; FMCSA–2008–0106; FMCSA–2010–0114; FMCSA–2012–0161], using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received

without change to <http://www.regulations.gov>, including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to <http://www.regulations.gov> at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: 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 Privacy Act Statement for the Federal Docket Management System (FDMS) published in the **Federal Register** on January 17, 2008 (73 FR 3316).

FOR FURTHER INFORMATION CONTACT:

Elaine M. Papp, Chief, Medical Programs Division, 202–366–4001, fmcamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:**Background**

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from the vision requirements in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce, for a two-year period if it finds “such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.” The procedures for requesting an exemption (including renewals) are set out in 49 CFR part 381.

Exemption Decision

This notice addresses 15 individuals who have requested renewal of their exemptions in accordance with FMCSA procedures. FMCSA has evaluated these 15 applications for renewal on their

merits and decided to extend each exemption for a renewable two-year period. They are:

Frank R. Berritto (NY), Thomas L. Corey (IN), James H. Facemyre (WV), Gregory L. Farrar (TX), Jeffrey M. Hall (AL), Clifford J. Harris (VA), Oskia D. Johnson (IN), Michael G. Martin (CT), Bobby L. Mashburn (GA), Aaron L. Paustian (IA), Larry A. Prieue (ND), Kenneth R. Riener (MT), Leon F. Stephens (CO), Patrick D. Talley (SC), Timothy J. Wilson (MD).

The exemptions are extended subject to the following conditions: (1) That each individual has a physical examination every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provides a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retains a copy of the certification on his/her person while driving for presentation to a duly authorized Federal, State, or local enforcement official. Each exemption will be valid for two years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two year periods. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 15 applicants has satisfied the entry conditions for obtaining an exemption from the vision requirements (64 FR 68195; 65 FR 20251; 67 FR 38311; 67 FR 46016; 67 FR 57267; 69 FR 26921; 69 FR 51346; 71 FR 14566; 71 FR 27033; 71 FR 30227; 71 FR 50970; 73 FR 6244; 73 FR 15568; 73 FR 16952; 73 FR 27014; 73 FR 27017; 73 FR 35197; 73 FR 42403; 73 FR 48270; 73 FR 48275; 75 FR 22179; 75 FR 27623; 75 FR 34212; 75 FR 38602; 75 FR 47888; 75 FR 50799; 77 FR 36338; 77 FR 40945; 77 FR

40946; 77 FR 41879; 77 FR 48590; 77 FR 52391). Each of these 15 applicants has requested renewal of the exemption and has submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements.

These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

Request for Comments

FMCSA will review comments received at any time concerning a particular driver's safety record and determine if the continuation of the exemption is consistent with the requirements at 49 U.S.C. 31136(e) and 31315. However, FMCSA requests that interested parties with specific data concerning the safety records of these drivers submit comments by September 5, 2014.

FMCSA believes that the requirements for a renewal of an exemption under 49 U.S.C. 31136(e) and 31315 can be satisfied by initially granting the renewal and then requesting and evaluating, if needed, subsequent comments submitted by interested parties. As indicated above, the Agency previously published notices of final disposition announcing its decision to exempt these 15 individuals from the vision requirement in 49 CFR 391.41(b)(10). The final decision to grant an exemption to each of these individuals was made on the merits of each case and made only after careful consideration of the comments received to its notices of applications. The notices of applications stated in detail the qualifications, experience, and medical condition of each applicant for an exemption from the vision requirements. That information is available by consulting the above cited **Federal Register** publications.

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is

being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

Submitting Comments

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov> and in the search box insert the docket numbers FMCSA-1999-6480; FMCSA-2002-12294; FMCSA-2006-24015; FMCSA-2007-0071; FMCSA-2008-0021; FMCSA-2008-0106; FMCSA-2010-0114; FMCSA-2012-0161 and click the search button. When the new screen appears, click on the blue "Comment Now!" button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period and may change this proposed rule based on your comments. FMCSA may issue a final rule at any time after the close of the comment period.

Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble, to submit your comment online, go to <http://www.regulations.gov> and in the search box insert the docket number FMCSA-1999-6480; FMCSA-2002-12294; FMCSA-2006-24015; FMCSA-2007-0071; FMCSA-2008-0021; FMCSA-2008-0106; FMCSA-2010-0114; FMCSA-2012-0161 and click "Search." Next, click "Open Docket Folder" and you will find all documents and comments related to the proposed rulemaking.

Issued on: July 29, 2014.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2014-18647 Filed 8-5-14; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Additional Designations, Foreign Narcotics Kingpin Designation Act

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of four individuals and one entity whose property and interests in property have been blocked pursuant to the Foreign Narcotics Kingpin Designation Act (Kingpin Act) (21 U.S.C. 1901-1908, 8 U.S.C. 1182).

DATES: The designation by the Director of OFAC of the four individuals and one entity identified in this notice pursuant to section 805(b) of the Kingpin Act is effective on July 29, 2014.

FOR FURTHER INFORMATION CONTACT:

Assistant Director, Sanctions Compliance & Evaluation, Office of Foreign Assets Control, U.S. Department of the Treasury, Washington, DC 20220, Tel: (202) 622-2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available on OFAC's Web site at <http://www.treasury.gov/ofac> or via facsimile through a 24-hour fax-on-demand service at (202) 622-0077.

Background

The Kingpin Act became law on December 3, 1999. The Kingpin Act establishes a program targeting the activities of significant foreign narcotics traffickers and their organizations on a worldwide basis. It provides a statutory framework for the imposition of sanctions against significant foreign narcotics traffickers and their organizations on a worldwide basis, with the objective of denying their businesses and agents access to the U.S. financial system and the benefits of trade and transactions involving U.S. companies and individuals.

The Kingpin Act blocks all property and interests in property, subject to U.S. jurisdiction, owned or controlled by significant foreign narcotics traffickers as identified by the President. In

addition, the Secretary of the Treasury, in consultation with the Attorney General, the Director of the Central Intelligence Agency, the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, the Secretary of State, and the Secretary of Homeland Security may designate and block the property and interests in property, subject to U.S. jurisdiction, of persons who are found to be: (1) Materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of a person designated pursuant to the Kingpin Act; (2) owned, controlled, or directed by, or acting for or on behalf of, a person designated pursuant to the Kingpin Act; or (3) playing a significant role in international narcotics trafficking.

On July 29, 2014, the Director of OFAC designated the following four individuals and one entity whose property and interests in property are

blocked pursuant to section 805(b) of the Kingpin Act.

Individuals

1. HU, Yongan; DOB 26 May 1976; POB China; citizen China; Passport E00957550 (China); National ID No. 410204197605261014 (China); Chinese Commercial Code 5170 3057 1344 (individual) [SDNTK] (Linked To: CEC LIMITED).
2. WANG, Guoying (a.k.a. WANG, Guo Ying); DOB 19 Mar 1950; citizen China; Passport G41966371 (China); Chinese Commercial Code 3769/0948/5931 (individual) [SDNTK] (Linked To: CEC LIMITED).
3. ZHANG, Lei (a.k.a. CHANG, Eric; a.k.a. LEI, Zhang; a.k.a. ZHANG, Shi); DOB 03 Jan 1976; POB Shanghai, China; citizen China; Passport G23851362 (China); alt. Passport W76048374 (China); National ID No. 320202197601030513 (China); Chinese Commercial Code 1728 4320 (individual) [SDNTK] (Linked To: CEC LIMITED).

4. ZHANG, Jicheng; DOB 12 Nov 1973; POB China; citizen China; Passport G60761595 (China); Chinese Commercial Code 1728 3444 2052 (individual) [SDNTK] (Linked To: CEC LIMITED).

Entity

5. CEC LIMITED (a.k.a. CEC CHEMICAL CO., LTD.; a.k.a. CEC LTD.; a.k.a. CEC PHARM CO LTD; a.k.a. CEC PHARMATECH LTD; a.k.a. CHINA ENRICHING CHEMISTRY; a.k.a. HANGZHOU HONGYAN TRADING CO., LTD; a.k.a. IAN LIMITED; a.k.a. SHANGHAI CANHE PHARMTECH CO LTD), Room 807, 8/F Building 6, No. 333 Guiping Road, Shanghai 200233, China; 401, No. 23, Changning Road 1277, Shanghai 200051, China; Web site www.cecchem.com; alt. Web site www.eric1234.com [SDNTK].

Dated: July 29, 2014.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. 2014-18554 Filed 8-5-14; 8:45 am]

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Part II

Department of Health and Human Services

Center for Medicare & Medicaid Services

42 CFR Part 412

Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2015; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 412**

[CMS-1608-F]

RIN 0938-AS09

Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2015**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule.

SUMMARY: This final rule updates the prospective payment rates for inpatient rehabilitation facilities (IRFs) for federal fiscal year (FY) 2015 as required by the statute. This final rule finalizes a policy to collect data on the amount and mode (that is, Individual, Concurrent, Group, and Co-Treatment) of therapy provided in the IRF setting according to therapy discipline, revises the list of diagnosis and impairment group codes that presumptively meet the “60 percent rule” compliance criteria, provides a way for IRFs to indicate on the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI) form whether the prior treatment and severity requirements have been met for arthritis cases to presumptively meet the “60 percent rule” compliance criteria, and revises and updates quality measures and reporting requirements under the IRF quality reporting program (QRP). This rule also delays the effective date for the revisions to the list of diagnosis codes that are used to determine presumptive compliance under the “60 percent rule” that were finalized in FY 2014 IRF PPS final rule and adopts the revisions to the list of diagnosis codes that are used to determine presumptive compliance under the “60 percent rule” that are finalized in this rule. This final rule also addresses the implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), for the IRF prospective payment system (PPS), which will be effective when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions.

DATES: The updated IRF prospective payment rates are applicable for IRF

discharges occurring on or after October 1, 2014, and on or before September 30, 2015 (FY 2015). In addition, the revisions to the list of diagnosis codes that are used to determine presumptive compliance under the “60 percent rule” that were finalized in FY 2014 IRF PPS final rule (78 FR 47860) and the revisions to the lists of diagnosis codes and impairment group codes finalized in this rule are applicable for compliance review periods beginning on or after October 1, 2015. The change to the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI) form to indicate whether the prior treatment and severity requirements have been met for arthritis cases to presumptively meet the “60 percent rule” compliance criteria is applicable October 1, 2015. The implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), for the IRF prospective payment system (PPS), is applicable when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions. The updated quality measures and reporting requirements under the IRF QRP are applicable for IRF discharges occurring on or after October 1, 2014. The two new IRF quality measures will require data submission beginning with admissions and discharges occurring on or after January 1, 2015: (1) National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); and (2) National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717).

FOR FURTHER INFORMATION CONTACT:

Gwendolyn Johnson, (410) 786-6954, for general information.

Charles Padgett, (410) 786-2811, for information about the quality reporting program.

Kadie Thomas, (410) 786-0468, or Susanne Seagrave, (410) 786-0044, for information about the payment policies and the proposed payment rates.

SUPPLEMENTARY INFORMATION: The IRF PPS Addenda along with other supporting documents and tables referenced in this final rule are available through the Internet on the CMS Web site at <http://www.cms.hhs.gov/>

Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/.

Executive Summary*A. Purpose*

This final rule updates the payment rates for IRFs for FY 2015 (that is, for discharges occurring on or after October 1, 2014, and on or before September 30, 2015) as required under section 1886(j)(3)(C) of the Social Security Act (the Act). Section 1886(j)(5) of the Act requires the Secretary to publish in the **Federal Register** on or before the August 1 that precedes the start of each fiscal year, the classification and weighting factors for the IRF PPS’s case-mix groups and a description of the methodology and data used in computing the prospective payment rates for that fiscal year. It also makes policy changes to programs associated with IRFs.

B. Summary of Major Provisions

In this final rule, we use the methods described in the FY 2014 IRF PPS final rule (78 FR 47860) to update the federal prospective payment rates for FY 2015 using updated FY 2013 IRF claims and the most recent available IRF cost report data. We are also finalizing a policy to collect data on the amount and mode (that is, Individual, Concurrent, Group, and Co-Treatment) of therapy provided in the IRF setting according to therapy discipline, revising the list of impairment group codes that presumptively meet the “60 percent rule” compliance criteria, providing a way for IRFs to indicate on the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI) form whether the prior treatment and severity requirements have been met for arthritis cases to presumptively meet the “60 percent rule” compliance criteria, and revising and updating quality measures and reporting requirements under the IRF QRP. In this final rule, we also address the implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), for the IRF prospective payment system (PPS), effective when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions.

C. Summary of Impacts

Provision description	Transfers
FY 2015 IRF PPS payment rate update	The overall economic impact of this final rule is an estimated \$180 million in increased payments from the Federal government to IRFs during FY 2015.
Provision description	Costs
New quality reporting program requirements	The total costs in FY 2015 for IRFs as a result of the new quality reporting requirements are estimated to be \$852,238
New Individual, Concurrent, Group, and Co-Treatment Therapy reporting requirements.	The total costs in FY 2016 for IRFs as a result of the new Individual, Concurrent, Group, and Co-Treatment reporting requirements are estimated to be \$1.2 million.

To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

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Acronyms, Abbreviations, and Short Forms

Because of the many terms to which we refer by acronym, abbreviation, or short form in this final rule, we are listing the acronyms, abbreviation, and short forms used and their corresponding terms in alphabetical order below.

- The Act The Social Security Act
- ADC Average Daily Census
- The Affordable Care Act Patient Protection and Affordable Care Act (Pub. L. 111-148, enacted on March 23, 2010)
- AHIMA American Health Information Management Association
- ASCA Administrative Simplification Compliance Act (Pub. L. 107-105, enacted on December 27, 2002)
- BBA Balanced Budget Act of 1997 (Pub. L. 105-33, enacted on August 5, 1997)
- BLS U.S. Bureau of Labor Statistics
- CAH Critical Access Hospitals
- CAUTI Catheter-Associated Urinary Tract Infection
- CBSA Core-Based Statistical Area
- CCR Cost-to-Charge Ratio
- CDC The Centers for Disease Control and Prevention
- CDI *Clostridium difficile* Infection
- CFR Code of Federal Regulations
- CMG Case-Mix Group
- CMS Centers for Medicare & Medicaid Services
- DRA Deficit Reduction Act of 2005 (Pub. L. 109-171, enacted February 8, 2006)
- DSH Disproportionate Share Hospital
- DSH PP Disproportionate Share Patient Percentage
- EHR Electronic Health Record
- ESRD End-Stage Renal Disease
- FR **Federal Register**
- FY Federal Fiscal Year
- GEMS General Equivalence Mappings
- HAI Healthcare Associated Infection
- HCP Health Care Personnel
- HHS U.S. Department of Health & Human Services
- HIE Health Information Exchange

HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191, enacted on August 21, 1996)

ICD–9–CM The International Classification of Diseases, 9th Revision, Clinical Modification

ICD–10–CM The International Classification of Diseases, 10th Revision, Clinical Modification

ICRs Information Collection Requirements

IGC Impairment Group Code

IGI IHS Global Insight

IPF Inpatient Psychiatric Facility

IPPS Inpatient Prospective Payment System

IQR Inpatient Quality Reporting Program

IRF Inpatient Rehabilitation Facility

IRF–PAI Inpatient Rehabilitation Facility–Patient Assessment Instrument

IRF PPS Inpatient Rehabilitation Facility Prospective Payment System

IRVEN Inpatient Rehabilitation Validation and Entry

LIP Low-Income Percentage

LPN Licensed Practical Nurse

LTCH Long-Term Care Hospital

MAC Medicare Administrative Contractor

MAP Measure Applications Partnership

MA (Medicare Part C) Medicare Advantage

MedPAC Medicare Payment Advisory Commission

MDS Minimum Data Set

MFP Multifactor Productivity

MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110–173, enacted on December 29, 2007)

MRSA Methicillin-Resistant *Staphylococcus aureus*

MUC Measures under Consideration

NHSN National Healthcare Safety Network

NPP National Priorities Partnership

NQF National Quality Forum

OMB Office of Management and Budget

ONC Office of the National Coordinator for Health Information Technology

PAI Patient Assessment Instrument

PPS Prospective Payment System

PRA Paperwork Reduction Act of 1995 (Pub. L. 104–13, enacted on May 22, 1995)

PRRB Provider Reimbursement Review Board

QM Quality Measure

QRP Quality Reporting Program

RIA Regulatory Impact Analysis

RIC Rehabilitation Impairment Category

RFA Regulatory Flexibility Act (Pub. L. 96–354, enacted on September 19, 1980)

RN Registered Nurse

RPL Rehabilitation, Psychiatric, and Long-Term Care market basket

SSI Supplemental Security Income

I. Background

A. Historical Overview of the Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS)

Section 1886(j) of the Act provides for the implementation of a per-discharge prospective payment system (PPS) for inpatient rehabilitation hospitals and inpatient rehabilitation units of a hospital (collectively, hereinafter referred to as IRFs). Payments under the IRF PPS encompass inpatient operating and capital costs of furnishing covered

rehabilitation services (that is, routine, ancillary, and capital costs), but not direct graduate medical education costs, costs of approved nursing and allied health education activities, bad debts, and other services or items outside the scope of the IRF PPS. Although a complete discussion of the IRF PPS provisions appears in the original FY 2002 IRF PPS final rule (66 FR 41316) and the FY 2006 IRF PPS final rule (70 FR 47880), we are providing below a general description of the IRF PPS for fiscal years (FYs) 2002 through 2013.

Under the IRF PPS from FY 2002 through FY 2005, as described in the FY 2002 IRF PPS final rule (66 FR 41316), the federal prospective payment rates were computed across 100 distinct case-mix groups (CMGs). We constructed 95 CMGs using rehabilitation impairment categories (RICs), functional status (both motor and cognitive), and age (in some cases, cognitive status and age may not be a factor in defining a CMG). In addition, we constructed five special CMGs to account for very short stays and for patients who expire in the IRF.

For each of the CMGs, we developed relative weighting factors to account for a patient's clinical characteristics and expected resource needs. Thus, the weighting factors accounted for the relative difference in resource use across all CMGs. Within each CMG, we created tiers based on the estimated effects that certain comorbidities would have on resource use.

We established the federal PPS rates using a standardized payment conversion factor (formerly referred to as the budget-neutral conversion factor). For a detailed discussion of the budget-neutral conversion factor, please refer to our FY 2004 IRF PPS final rule (68 FR 45684 through 45685). In the FY 2006 IRF PPS final rule (70 FR 47880), we discussed in detail the methodology for determining the standard payment conversion factor.

We applied the relative weighting factors to the standard payment conversion factor to compute the unadjusted federal prospective payment rates under the IRF PPS from FYs 2002 through 2005. Within the structure of the payment system, we then made adjustments to account for interrupted stays, transfers, short stays, and deaths. Finally, we applied the applicable adjustments to account for geographic variations in wages (wage index), the percentage of low-income patients, location in a rural area (if applicable), and outlier payments (if applicable) to the IRFs' unadjusted federal prospective payment rates.

For cost reporting periods that began on or after January 1, 2002, and before

October 1, 2002, we determined the final prospective payment amounts using the transition methodology prescribed in section 1886(j)(1) of the Act. Under this provision, IRFs transitioning into the PPS were paid a blend of the federal IRF PPS rate and the payment that the IRFs would have received had the IRF PPS not been implemented. This provision also allowed IRFs to elect to bypass this blended payment and immediately be paid 100 percent of the federal IRF PPS rate. The transition methodology expired as of cost reporting periods beginning on or after October 1, 2002 (FY 2003), and payments for all IRFs now consist of 100 percent of the federal IRF PPS rate.

We established a CMS Web site as a primary information resource for the IRF PPS which is available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/index.html>. The Web site may be accessed to download or view publications, software, data specifications, educational materials, and other information pertinent to the IRF PPS.

Section 1886(j) of the Act confers broad statutory authority upon the Secretary to propose refinements to the IRF PPS. In the FY 2006 IRF PPS final rule (70 FR 47880) and in correcting amendments to the FY 2006 IRF PPS final rule (70 FR 57166) that we published on September 30, 2005, we finalized a number of refinements to the IRF PPS case-mix classification system (the CMGs and the corresponding relative weights) and the case-level and facility-level adjustments. These refinements included the adoption of the Office of Management and Budget's (OMB) Core-Based Statistical Area (CBSA) market definitions, modifications to the CMGs, tier comorbidities, and CMG relative weights, implementation of a new teaching status adjustment for IRFs, revision and rebasing of the market basket index used to update IRF payments, and updates to the rural, low-income percentage (LIP), and high-cost outlier adjustments. Beginning with the FY 2006 IRF PPS final rule (70 FR 47908 through 47917), the market basket index used to update IRF payments is a market basket reflecting the operating and capital cost structures for freestanding IRFs, freestanding inpatient psychiatric facilities (IPFs), and long-term care hospitals (LTCHs) (hereafter referred to as the rehabilitation, psychiatric, and long-term care (RPL) market basket). Any reference to the FY 2006 IRF PPS final rule in this final rule also includes the provisions effective in the correcting

amendments. For a detailed discussion of the final key policy changes for FY 2006, please refer to the FY 2006 IRF PPS final rule (70 FR 47880 and 70 FR 57166).

In the FY 2007 IRF PPS final rule (71 FR 48354), we further refined the IRF PPS case-mix classification system (the CMG relative weights) and the case-level adjustments, to ensure that IRF PPS payments would continue to reflect as accurately as possible the costs of care. For a detailed discussion of the FY 2007 policy revisions, please refer to the FY 2007 IRF PPS final rule (71 FR 48354).

In the FY 2008 IRF PPS final rule (72 FR 44284), we updated the federal prospective payment rates and the outlier threshold, revised the IRF wage index policy, and clarified how we determine high-cost outlier payments for transfer cases. For more information on the policy changes implemented for FY 2008, please refer to the FY 2008 IRF PPS final rule (72 FR 44284), in which we published the final FY 2008 IRF federal prospective payment rates.

After publication of the FY 2008 IRF PPS final rule (72 FR 44284), section 115 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 110–173, enacted on December 29, 2007) (MMSEA), amended section 1886(j)(3)(C) of the Act to apply a zero percent increase factor for FYs 2008 and 2009, effective for IRF discharges occurring on or after April 1, 2008. Section 1886(j)(3)(C) of the Act required the Secretary to develop an increase factor to update the IRF federal prospective payment rates for each FY. Based on the legislative change to the increase factor, we revised the FY 2008 federal prospective payment rates for IRF discharges occurring on or after April 1, 2008. Thus, the final FY 2008 IRF federal prospective payment rates that were published in the FY 2008 IRF PPS final rule (72 FR 44284) were effective for discharges occurring on or after October 1, 2007, and on or before March 31, 2008; and the revised FY 2008 IRF federal prospective payment rates were effective for discharges occurring on or after April 1, 2008, and on or before September 30, 2008. The revised FY 2008 federal prospective payment rates are available on the CMS Web site at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html>.

In the FY 2009 IRF PPS final rule (73 FR 46370), we updated the CMG relative weights, the average length of stay values, and the outlier threshold; clarified IRF wage index policies regarding the treatment of “New

England deemed” counties and multi-campus hospitals; and revised the regulation text in response to section 115 of the MMSEA to set the IRF compliance percentage at 60 percent (the “60 percent rule”) and continue the practice of including comorbidities in the calculation of compliance percentages. We also applied a zero percent market basket increase factor for FY 2009 in accordance with section 115 of the MMSEA. For more information on the policy changes implemented for FY 2009, please refer to the FY 2009 IRF PPS final rule (73 FR 46370), in which we published the final FY 2009 IRF federal prospective payment rates.

In the FY 2010 IRF PPS final rule (74 FR 39762) and in correcting amendments to the FY 2010 IRF PPS final rule (74 FR 50712) that we published on October 1, 2009, we updated the federal prospective payment rates, the CMG relative weights, the average length of stay values, the rural, LIP, teaching status adjustment factors, and the outlier threshold; implemented new IRF coverage requirements for determining whether an IRF claim is reasonable and necessary; and revised the regulation text to require IRFs to submit patient assessments on Medicare Advantage (MA) (Medicare Part C) patients for use in the 60 percent rule calculations. Any reference to the FY 2010 IRF PPS final rule in this final rule also includes the provisions effective in the correcting amendments. For more information on the policy changes implemented for FY 2010, please refer to the FY 2010 IRF PPS final rule (74 FR 39762 and 74 FR 50712), in which we published the final FY 2010 IRF federal prospective payment rates.

After publication of the FY 2010 IRF PPS final rule (74 FR 39762), section 3401(d) of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted on March 23, 2010), as amended by section 10319 of the same Act and by section 1105 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted on March 30, 2010) (collectively, hereafter referred to as “The Affordable Care Act”), amended section 1886(j)(3)(C) of the Act and added section 1886(j)(3)(D) of the Act. Section 1886(j)(3)(C) of the Act requires the Secretary to estimate a multi-factor productivity adjustment to the market basket increase factor, and to apply other adjustments as defined by the Act. The productivity adjustment applies to FYs from 2012 forward. The other adjustments apply to FYs 2010 to 2019.

Sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(i) of the Act defined the

adjustments that were to be applied to the market basket increase factors in FYs 2010 and 2011. Under these provisions, the Secretary was required to reduce the market basket increase factor in FY 2010 by a 0.25 percentage point adjustment. Notwithstanding this provision, in accordance with section 3401(p) of the Affordable Care Act, the adjusted FY 2010 rate was only to be applied to discharges occurring on or after April 1, 2010. Based on the self-implementing legislative changes to section 1886(j)(3) of the Act, we adjusted the FY 2010 federal prospective payment rates as required, and applied these rates to IRF discharges occurring on or after April 1, 2010, and on or before September 30, 2010. Thus, the final FY 2010 IRF federal prospective payment rates that were published in the FY 2010 IRF PPS final rule (74 FR 39762) were used for discharges occurring on or after October 1, 2009, and on or before March 31, 2010, and the adjusted FY 2010 IRF federal prospective payment rates applied to discharges occurring on or after April 1, 2010, and on or before September 30, 2010. The adjusted FY 2010 federal prospective payment rates are available on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html>.

In addition, sections 1886(j)(3)(C) and (D) of the Act also affected the FY 2010 IRF outlier threshold amount because they required an adjustment to the FY 2010 RPL market basket increase factor, which changed the standard payment conversion factor for FY 2010. Specifically, the original FY 2010 IRF outlier threshold amount was determined based on the original estimated FY 2010 RPL market basket increase factor of 2.5 percent and the standard payment conversion factor of \$13,661. However, as adjusted, the IRF prospective payments are based on the adjusted RPL market basket increase factor of 2.25 percent and the revised standard payment conversion factor of \$13,627. To maintain estimated outlier payments for FY 2010 equal to the established standard of 3 percent of total estimated IRF PPS payments for FY 2010, we revised the IRF outlier threshold amount for FY 2010 for discharges occurring on or after April 1, 2010, and on or before September 30, 2010. The revised IRF outlier threshold amount for FY 2010 was \$10,721.

Sections 1886(j)(3)(c)(ii)(II) and 1886(j)(3)(D)(i) of the Act also required the Secretary to reduce the market basket increase factor in FY 2011 by a 0.25 percentage point adjustment. The FY 2011 IRF PPS notice (75 FR 42836)

and the correcting amendments to the FY 2011 IRF PPS notice (75 FR 70013) described the required adjustments to the FY 2011 and FY 2010 IRF PPS federal prospective payment rates and outlier threshold amount for IRF discharges occurring on or after April 1, 2010, and on or before September 30, 2011. It also updated the FY 2011 federal prospective payment rates, the CMG relative weights, and the average length of stay values. Any reference to the FY 2011 IRF PPS notice in this final rule also includes the provisions effective in the correcting amendments. For more information on the FY 2010 and FY 2011 adjustments or the updates for FY 2011, please refer to the FY 2011 IRF PPS notice (75 FR 42836 and 75 FR 70013).

In the FY 2012 IRF PPS final rule (76 FR 47836), we updated the IRF federal prospective payment rates, rebased and revised the RPL market basket, and established a new quality reporting program for IRFs in accordance with section 1886(j)(7) of the Act. We also revised regulation text for the purpose of updating and providing greater clarity. For more information on the policy changes implemented for FY 2012, please refer to the FY 2012 IRF PPS final rule (76 FR 47836), in which we published the final FY 2012 IRF federal prospective payment rates.

The FY 2013 IRF PPS notice (77 FR 44618) described the required adjustments to the FY 2013 federal prospective payment rates and outlier threshold amount for IRF discharges occurring on or after October 1, 2012, and on or before September 30, 2013. It also updated the FY 2013 federal prospective payment rates, the CMG relative weights, and the average length of stay values. For more information on the updates for FY 2013, please refer to the FY 2013 IRF PPS notice (77 FR 44618).

In the FY 2014 IRF PPS final rule (78 FR 47860), we updated the federal prospective payment rates, the CMG relative weights, and the outlier threshold amount. We also updated the facility-level adjustment factors using an enhanced estimation methodology, revised the list of diagnosis codes that count toward an IRF's 60 percent rule compliance calculation to determine "presumptive compliance," revised sections of the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI), revised requirements for acute care hospitals that have IRF units, clarified the IRF regulation text regarding limitation of review, updated references to previously changed sections in the regulations text, and revised and updated quality measures

and reporting requirements under the IRF quality reporting program. For more information on the policy changes implemented for FY 2014, please refer to the FY 2014 IRF PPS final rule (78 FR 47860), in which we published the final FY 2014 IRF federal prospective payment rates.

B. Provisions of the Affordable Care Act Affecting the IRF PPS in FY 2012 and Beyond

The Affordable Care Act included several provisions that affect the IRF PPS in FYs 2012 and beyond. In addition to what was discussed above, section 3401(d) of the Affordable Care Act also added section 1886(j)(3)(C)(ii)(I) (providing for a "productivity adjustment" for fiscal year 2012 and each subsequent fiscal year). The productivity adjustment for FY 2015 is discussed in section VI.A. of this final rule. Section 3401(d) of the Affordable Care Act requires an additional 0.2 percentage point adjustment to the IRF increase factor for FY 2015, as discussed in section VI.A. of this final rule. Section 1886(j)(3)(C)(ii)(II) of the Act notes that the application of these adjustments to the market basket update may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year.

Section 3004(b) of the Affordable Care Act also addressed the IRF PPS program. It reassigned the previously designated section 1886(j)(7) of the Act to section 1886(j)(8) and inserted a new section 1886(j)(7), which contains requirements for the Secretary to establish a quality reporting program for IRFs. Under that program, data must be submitted in a form and manner and at a time specified by the Secretary. Beginning in FY 2014, section 1886(j)(7)(A)(i) of the Act requires the application of a 2 percentage point reduction of the applicable market basket increase factor for IRFs that fail to comply with the quality data submission requirements. Application of the 2 percentage point reduction may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Reporting-based reductions to the market basket increase factor will not be cumulative; they will only apply for the FY involved.

Under section 1886(j)(7)(D)(i) and (ii) of the Act, the Secretary is generally required to select quality measures for the IRF quality reporting program from those that have been endorsed by the consensus-based entity which holds a

performance measurement contract under section 1890(a) of the Act. This contract is currently held by the National Quality Forum (NQF). So long as due consideration is given to measures that have been endorsed or adopted by a consensus-based organization, section 1886(j)(7)(D)(ii) of the Act authorizes the Secretary to select non-endorsed measures for specified areas or medical topics when there are no feasible or practical endorsed measure(s).

Section 1886(j)(7)(E) of the Act requires the Secretary to establish procedures for making the IRF PPS quality reporting data available to the public. In so doing, the Secretary must ensure that IRFs have the opportunity to review any such data prior to its release to the public. Future rulemaking will address these public reporting obligations.

C. Operational Overview of the Current IRF PPS

As described in the FY 2002 IRF PPS final rule, upon the admission and discharge of a Medicare Part A Fee-for-Service patient, the IRF is required to complete the appropriate sections of a patient assessment instrument (PAI), designated as the IRF-PAI. In addition, beginning with IRF discharges occurring on or after October 1, 2009, the IRF is also required to complete the appropriate sections of the IRF-PAI upon the admission and discharge of each Medicare Part C (Medicare Advantage) patient, as described in the FY 2010 IRF PPS final rule. All required data must be electronically encoded into the IRF-PAI software product. Generally, the software product includes patient classification programming called the Grouper software. The Grouper software uses specific IRF-PAI data elements to classify (or group) patients into distinct CMGs and account for the existence of any relevant comorbidities.

The Grouper software produces a 5-character CMG number. The first character is an alphabetic character that indicates the comorbidity tier. The last 4 characters are numeric characters that represent the distinct CMG number. Free downloads of the Inpatient Rehabilitation Validation and Entry (IRVEN) software product, including the Grouper software, are available on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html>.

Once a Medicare Fee-for-Service Part A patient is discharged, the IRF submits a Medicare claim as a Health Insurance Portability and Accountability Act of

1996 (Pub. L. 104–191, enacted on August 21, 1996) (HIPAA) compliant electronic claim or, if the Administrative Simplification Compliance Act of 2002 (Pub. L. 107–105, enacted on December 27, 2002) (ASCA) permits, a paper claim (a UB–04 or a CMS–1450 as appropriate) using the five-character CMG number and sends it to the appropriate Medicare Administrative Contractor (MAC). In addition, once a Medicare Advantage patient is discharged, in accordance with the Medicare Claims Processing Manual, chapter 3, section 20.3 (Pub. 100–04), hospitals (including IRFs) must submit an informational-only bill (TOB 111), which includes Condition Code 04 to their MAC. This will ensure that the Medicare Advantage days are included in the hospital's Supplemental Security Income (SSI) ratio (used in calculating the IRF low-income percentage adjustment) for Fiscal Year 2007 and beyond. Claims submitted to Medicare must comply with both ASCA and HIPAA.

Section 3 of the ASCA amends section 1862(a) of the Act by adding paragraph (22) which requires the Medicare program, subject to section 1862(h) of the Act, to deny payment under Part A or Part B for any expenses for items or services “for which a claim is submitted other than in an electronic form specified by the Secretary.” Section 1862(h) of the Act, in turn, provides that the Secretary shall waive such denial in situations in which there is no method available for the submission of claims in an electronic form or the entity submitting the claim is a small provider. In addition, the Secretary also has the authority to waive such denial “in such unusual cases as the Secretary finds appropriate.” For more information, see the “Medicare Program; Electronic Submission of Medicare Claims” final rule (70 FR 71008). Our instructions for the limited number of Medicare claims submitted on paper are available at <http://www.cms.gov/manuals/downloads/clm104c25.pdf>.

Section 3 of the ASCA operates in the context of the administrative simplification provisions of HIPAA, which include, among others, the requirements for transaction standards and code sets codified in 45 CFR, parts 160 and 162, subparts A and I through R (generally known as the Transactions Rule). The Transactions Rule requires covered entities, including covered health care providers, to conduct covered electronic transactions according to the applicable transaction standards. (See the CMS program claim memoranda at <http://www.cms.gov/ElectronicBillingEDITrans/> and listed in

the addenda to the Medicare Intermediary Manual, Part 3, section 3600).

The MAC processes the claim through its software system. This software system includes pricing programming called the “Pricer” software. The Pricer software uses the CMG number, along with other specific claim data elements and provider-specific data, to adjust the IRF's prospective payment for interrupted stays, transfers, short stays, and deaths, and then applies the applicable adjustments to account for the IRF's wage index, percentage of low-income patients, rural location, and outlier payments. For discharges occurring on or after October 1, 2005, the IRF PPS payment also reflects the teaching status adjustment that became effective as of FY 2006, as discussed in the FY 2006 IRF PPS final rule (70 FR 47880).

II. Summary of Provisions of the Proposed Rule

In the FY 2015 IRF PPS proposed rule (79 FR 26308), we proposed to update the IRF Federal prospective payment rates, to collect data on the amount and mode (that is, Individual, Group, and Co-Treatment) of therapies provided in the IRF setting according to therapy discipline, to revise the list of diagnosis and impairment group codes that presumptively meet the 60 percent rule compliance criteria, provide for a new item on the IRF–PAI form to indicate whether the prior treatment and severity requirements have been met for arthritis cases to presumptively meet the 60 percent rule compliance criteria, and to revise and update quality measures and reporting requirements under the IRF QRP. In the FY 2015 IRF PPS proposed rule (79 FR 26308), we also addressed the implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM), for the IRF prospective payment system (PPS), effective when ICD–10–CM becomes the required medical data code set for use on Medicare claims and IRF–PAI submissions.

The proposed updates to the IRF federal prospective payment rates for FY 2015 were as follows:

- Update the FY 2015 IRF PPS relative weights and average length of stay values using the most current and complete Medicare claims and cost report data in a budget-neutral manner, as discussed in section III of the FY 2015 IRF PPS proposed rule (79 FR 26308, 26314 through 26318).
- Discuss our rationale for freezing the IRF facility-level adjustment factors at FY 2014 levels, as discussed in

section IV of the FY 2015 IRF PPS proposed rule (79 FR 26308, 26318 through 26319).

- Update the FY 2015 IRF PPS payment rates by the proposed market basket increase factor, based upon the most current data available, with a 0.2 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act and a proposed productivity adjustment required by section 1886(j)(3)(C)(ii)(I) of the Act, as described in section V of the FY 2015 IRF PPS proposed rule (79 FR 26308, 26319 through 26321).

- Discuss the Secretary's Proposed Recommendation for updating IRF PPS payments for FY 2015, in accordance with the statutory requirements, as described in section V of the FY 2015 IRF PPS proposed rule (79 FR 26308 at 26321).

- Update the FY 2015 IRF PPS payment rates by the FY 2015 wage index and the labor-related share in a budget-neutral manner, as discussed in section V of the FY 2015 IRF PPS proposed rule (79 FR 26308, 26321 through 26322).

- Describe the calculation of the IRF Standard Payment Conversion Factor for FY 2015, as discussed in section V of the FY 2015 IRF PPS proposed rule (79 FR 26308 at 26322).

- Update the outlier threshold amount for FY 2015, as discussed in section VI of the FY 2015 IRF PPS proposed rule (79 FR 26308, 26324 through 26325).

- Update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2015, as discussed in section VI of the FY 2015 IRF PPS proposed rule (79 FR 26308 at 26325).

- Describe proposed revisions to the list of eligible diagnosis codes that are used to determine presumptive compliance under the 60 percent rule in section VII of the FY 2015 IRF PPS proposed rule (79 FR 26308 at 26327).

- Describe proposed revisions to the list of eligible impairment group codes that presumptively meet the 60 percent rule compliance criteria in section VII of the FY 2015 IRF PPS proposed rule (79 FR 26308, 26328 through 26329).

- Describe proposed data collection of the amount and mode (that is, of Individual, Group, and Co-Treatment) of therapies provided in IRFs according to occupational, speech, and physical therapy disciplines via the IRF–PAI in section VIII of the FY 2015 IRF PPS proposed rule (79 FR 26308, 26329 through 26330).

- Describe a proposed revision to the IRF–PAI to add a new data item for arthritis conditions in section IX of the

FY 2015 IRF PPS proposed rule (79 FR 26308, 26330 through 26331).

- Describe the conversion of the IRF PPS to ICD-10-CM, effective when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions, in section X of the FY 2015 IRF PPS proposed rule (79 FR 26308, 26331 through 26333).

- Describe proposed revisions and updates to quality measures and reporting requirements under the quality reporting program for IRFs in accordance with section 1886(j)(7) of the Act, as discussed in section XI of the FY 2015 IRF PPS proposed rule (79 FR 26308, 26333 through 26345).

III. Analysis and Responses to Public Comments

We received 66 timely responses from the public, many of which contained multiple comments on the FY 2015 IRF PPS proposed rule (79 FR 26308). We received comments from various trade associations, inpatient rehabilitation facilities, individual physicians, therapists, clinicians, health care industry organizations, law firms and health care consulting firms. The following sections, arranged by subject area, include a summary of the public comments that we received, and our responses.

IV. Update to the Case-Mix Group (CMG) Relative Weights and Average Length of Stay Values for FY 2015

As specified in § 412.620(b)(1), we calculate a relative weight for each CMG that is proportional to the resources needed by an average inpatient rehabilitation case in that CMG. For example, cases in a CMG with a relative weight of 2, on average, will cost twice as much as cases in a CMG with a relative weight of 1. Relative weights account for the variance in cost per discharge due to the variance in resource utilization among the payment groups, and their use helps to ensure that IRF PPS payments support beneficiary access to care, as well as provider efficiency.

In the FY 2015 IRF PPS proposed rule (79 FR 26308, 26314 through 26318), we proposed to update the CMG relative weights and average length of stay values for FY 2015. As required by statute, we always use the most recent available data to update the CMG relative weights and average lengths of stay. For FY 2015, we proposed to use the FY 2013 IRF claims and FY 2012 IRF cost report data. These data are the most current and complete data available at this time. Currently, only a small portion of the FY 2013 IRF cost report data are available for analysis, but the majority of the FY 2013 IRF claims data are available for analysis.

In the FY 2015 IRF PPS proposed rule (79 FR 26308, 26314 through 26318), we proposed to apply these data using the same methodologies that we have used to update the CMG relative weights and average length of stay values each fiscal year since we implemented an update to the methodology to use the more detailed cost-to-charge ratio (CCRs) data from the cost reports of IRF subprovider units of primary acute care hospitals, instead of CCR data from the associated primary care hospitals, to calculate IRFs' average costs per case, as discussed in the FY 2009 IRF PPS final rule (73 FR 46372). In calculating the CMG relative weights, we use a hospital-specific relative value method to estimate operating (routine and ancillary services) and capital costs of IRFs. The process used to calculate the CMG relative weights for this proposed rule is as follows:

Step 1. We estimate the effects that comorbidities have on costs.

Step 2. We adjust the cost of each Medicare discharge (case) to reflect the effects found in the first step.

Step 3. We use the adjusted costs from the second step to calculate CMG relative weights, using the hospital-specific relative value method.

Step 4. We normalize the FY 2015 CMG relative weights to the same average CMG relative weight from the CMG relative weights implemented in

the FY 2014 IRF PPS final rule (78 FR 47860).

Consistent with the methodology that we have used to update the IRF classification system in each instance in the past, we proposed to update the CMG relative weights for FY 2015 in such a way that total estimated aggregate payments to IRFs for FY 2015 are the same with or without the changes (that is, in a budget-neutral manner) by applying a budget neutrality factor to the standard payment amount. To calculate the appropriate budget neutrality factor for use in updating the FY 2015 CMG relative weights, we use the following steps:

Step 1. Calculate the estimated total amount of IRF PPS payments for FY 2015 (with no changes to the CMG relative weights).

Step 2. Calculate the estimated total amount of IRF PPS payments for FY 2015 by applying the changes to the CMG relative weights (as discussed above).

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2 to determine the budget neutrality factor (1.0000) that would maintain the same total estimated aggregate payments in FY 2015 with and without the changes to the CMG relative weights.

Step 4. Apply the budget neutrality factor (1.0000) to the FY 2014 IRF PPS standard payment amount after the application of the budget-neutral wage adjustment factor.

In section VI.F. of this final rule, we discuss the use of the existing methodology to calculate the standard payment conversion factor for FY 2015.

Table 1, "Relative Weights and Average Length of Stay Values for Case-Mix Groups," presents the CMGs, the comorbidity tiers, the corresponding relative weights, and the average length of stay values for each CMG and tier for FY 2015. The average length of stay for each CMG is used to determine when an IRF discharge meets the definition of a short-stay transfer, which results in a per diem case level adjustment.

TABLE 1—RELATIVE WEIGHTS AND AVERAGE LENGTH OF STAY VALUES FOR CASE-MIX GROUPS

CMG	CMG description (M=motor, C=cognitive, A=age)	Relative weight				Average length of stay			
		Tier 1	Tier 2	Tier 3	None	Tier 1	Tier 2	Tier 3	None
0101	Stroke M>51.05	0.7853	0.7150	0.6512	0.6248	9	10	8	8
0102	Stroke M>44.45 and M<51.05 and C>18.5.	0.9836	0.8955	0.8155	0.7826	11	11	10	10
0103	Stroke M>44.45 and M<51.05 and C<18.5.	1.1636	1.0594	0.9648	0.9258	12	14	12	12
0104	Stroke M>38.85 and M<44.45	1.2121	1.1036	1.0050	0.9644	13	13	12	12
0105	Stroke M>34.25 and M<38.85	1.4155	1.2888	1.1737	1.1262	14	14	14	14
0106	Stroke M>30.05 and M<34.25	1.6135	1.4691	1.3379	1.2838	16	16	15	15
0107	Stroke M>26.15 and M<30.05	1.8026	1.6412	1.4946	1.4342	17	19	17	17

TABLE 1—RELATIVE WEIGHTS AND AVERAGE LENGTH OF STAY VALUES FOR CASE-MIX GROUPS—Continued

CMG	CMG description (M=motor, C=cognitive, A=age)	Relative weight				Average length of stay			
		Tier 1	Tier 2	Tier 3	None	Tier 1	Tier 2	Tier 3	None
0108	Stroke M<26.15 and A>84.5 ..	2.2467	2.0456	1.8629	1.7876	22	24	21	21
0109	Stroke M>22.35 and M<26.15 and A<84.5.	2.0570	1.8728	1.7055	1.6366	19	20	19	19
0110	Stroke M<22.35 and A<84.5 ..	2.6928	2.4518	2.2328	2.1425	28	27	24	24
0201	Traumatic brain injury M>53.35 and C>23.5.	0.8145	0.6636	0.5954	0.5680	10	9	8	8
0202	Traumatic brain injury M>44.25 and M<53.35 and C>23.5.	1.0591	0.8629	0.7741	0.7385	12	10	9	10
0203	Traumatic brain injury M>44.25 and C<23.5.	1.2162	0.9909	0.8890	0.8481	13	12	12	11
0204	Traumatic brain injury M>40.65 and M<44.25.	1.3397	1.0915	0.9793	0.9342	12	13	12	12
0205	Traumatic brain injury M>28.75 and M<40.65.	1.5924	1.2974	1.1640	1.1104	14	15	14	14
0206	Traumatic brain injury M>22.05 and M<28.75.	1.9327	1.5747	1.4127	1.3477	19	18	16	16
0207	Traumatic brain injury M<22.05.	2.5640	2.0890	1.8741	1.7880	32	25	21	20
0301	Non-traumatic brain injury M>41.05.	1.1022	0.9324	0.8453	0.7798	10	11	10	10
0302	Non-traumatic brain injury M>35.05 and M<41.05.	1.3799	1.1673	1.0582	0.9762	13	13	12	12
0303	Non-traumatic brain injury M>26.15 and M<35.05.	1.6371	1.3849	1.2555	1.1583	16	15	14	14
0304	Non-traumatic brain injury M<26.15.	2.1541	1.8222	1.6520	1.5240	23	21	18	17
0401	Traumatic spinal cord injury M>48.45.	1.0264	0.8790	0.8131	0.7251	12	12	10	9
0402	Traumatic spinal cord injury M>30.35 and M<48.45.	1.4108	1.2081	1.1176	0.9966	15	14	14	13
0403	Traumatic spinal cord injury M>16.05 and M<30.35.	2.3059	1.9747	1.8268	1.6289	26	21	20	20
0404	Traumatic spinal cord injury M<16.05 and A>63.5.	4.0832	3.4967	3.2348	2.8845	54	40	33	33
0405	Traumatic spinal cord injury M<16.05 and A<63.5.	3.3355	2.8564	2.6425	2.3563	26	34	29	27
0501	Non-traumatic spinal cord in- jury M>51.35.	0.8418	0.6804	0.6237	0.5643	9	10	9	8
0502	Non-traumatic spinal cord in- jury M>40.15 and M<51.35.	1.1580	0.9359	0.8579	0.7763	11	12	10	10
0503	Non-traumatic spinal cord in- jury M>31.25 and M<40.15.	1.4373	1.1616	1.0648	0.9635	15	13	13	12
0504	Non-traumatic spinal cord in- jury M>29.25 and M<31.25.	1.6935	1.3687	1.2546	1.1352	17	15	15	14
0505	Non-traumatic spinal cord in- jury M>23.75 and M<29.25.	1.9365	1.5651	1.4346	1.2981	20	17	17	16
0506	Non-traumatic spinal cord in- jury M<23.75.	2.7066	2.1875	2.0052	1.8144	26	25	23	21
0601	Neurological M>47.75	1.0293	0.8149	0.7526	0.6862	9	10	9	9
0602	Neurological M>37.35 and M<47.75.	1.3283	1.0516	0.9713	0.8856	12	12	11	11
0603	Neurological M>25.85 and M<37.35.	1.6727	1.3243	1.2231	1.1152	15	15	13	13
0604	Neurological M<25.85	2.1908	1.7345	1.6020	1.4607	21	19	17	17
0701	Fracture of lower extremity M>42.15.	0.9700	0.8060	0.7727	0.7036	10	9	10	9
0702	Fracture of lower extremity M>34.15 and M<42.15.	1.2429	1.0327	0.9901	0.9016	13	12	12	11
0703	Fracture of lower extremity M>28.15 and M<34.15.	1.5056	1.2511	1.1994	1.0922	15	15	14	13
0704	Fracture of lower extremity M<28.15.	1.9359	1.6086	1.5421	1.4044	19	18	17	17
0801	Replacement of lower extrem- ity joint M>49.55.	0.7402	0.6068	0.5608	0.5172	8	8	7	7
0802	Replacement of lower extrem- ity joint M>37.05 and M<49.55.	0.9891	0.8109	0.7495	0.6912	10	10	9	9

TABLE 1—RELATIVE WEIGHTS AND AVERAGE LENGTH OF STAY VALUES FOR CASE-MIX GROUPS—Continued

CMG	CMG description (M=motor, C=cognitive, A=age)	Relative weight				Average length of stay			
		Tier 1	Tier 2	Tier 3	None	Tier 1	Tier 2	Tier 3	None
0803	Replacement of lower extremity joint M>28.65 and M<37.05 and A>83.5.	1.3374	1.0963	1.0133	0.9345	13	13	12	12
0804	Replacement of lower extremity joint M>28.65 and M<37.05 and A<83.5.	1.1821	0.9690	0.8956	0.8260	12	12	11	10
0805	Replacement of lower extremity joint M>22.05 and M<28.65.	1.4702	1.2053	1.1140	1.0274	14	14	13	12
0806	Replacement of lower extremity joint M<22.05.	1.7663	1.4479	1.3383	1.2342	16	17	15	14
0901	Other orthopedic M>44.75	0.9386	0.7581	0.7069	0.6392	10	9	9	8
0902	Other orthopedic M>34.35 and M<44.75.	1.2382	1.0000	0.9325	0.8432	12	12	11	10
0903	Other orthopedic M>24.15 and M<34.35.	1.5552	1.2561	1.1713	1.0591	15	15	14	13
0904	Other orthopedic M<24.15	1.9772	1.5968	1.4890	1.3464	19	18	17	16
1001	Amputation, lower extremity M>47.65.	1.0224	0.9300	0.8055	0.7365	11	12	10	10
1002	Amputation, lower extremity M>36.25 and M<47.65.	1.3168	1.1978	1.0374	0.9485	14	14	12	11
1003	Amputation, lower extremity M<36.25.	1.8778	1.7081	1.4794	1.3527	18	19	17	16
1101	Amputation, non-lower extremity M>36.35.	1.2643	1.0143	1.0050	0.8569	12	13	12	10
1102	Amputation, non-lower extremity M<36.35.	1.8936	1.5192	1.5052	1.2835	17	19	16	15
1201	Osteoarthritis M>37.65	1.0034	0.9522	0.8881	0.8256	10	11	11	10
1202	Osteoarthritis M>30.75 and M<37.65.	1.1916	1.1308	1.0547	0.9805	11	12	12	12
1203	Osteoarthritis M<30.75	1.5133	1.4360	1.3393	1.2452	13	16	15	15
1301	Rheumatoid, other arthritis M>36.35.	1.2220	0.9887	0.8677	0.8181	12	12	10	10
1302	Rheumatoid, other arthritis M>26.15 and M<36.35.	1.5913	1.2874	1.1299	1.0653	17	14	13	13
1303	Rheumatoid, other arthritis M<26.15.	2.0302	1.6425	1.4416	1.3591	18	19	16	15
1401	Cardiac M>48.85	0.9032	0.7324	0.6671	0.6051	9	10	8	8
1402	Cardiac M>38.55 and M<48.85.	1.1947	0.9689	0.8825	0.8004	12	11	11	10
1403	Cardiac M>31.15 and M<38.55.	1.4699	1.1920	1.0857	0.9847	14	13	12	12
1404	Cardiac M<31.15	1.8493	1.4998	1.3660	1.2390	18	17	15	14
1501	Pulmonary M>49.25	0.9998	0.8150	0.7537	0.7283	10	10	9	8
1502	Pulmonary M>39.05 and M<49.25.	1.2986	1.0586	0.9791	0.9461	13	11	11	10
1503	Pulmonary M>29.15 and M<39.05.	1.5918	1.2976	1.2001	1.1597	15	14	13	13
1504	Pulmonary M<29.15	1.9688	1.6049	1.4843	1.4343	20	17	15	15
1601	Pain syndrome M>37.15	0.9445	0.8763	0.8085	0.7620	10	10	9	10
1602	Pain syndrome M>26.75 and M<37.15.	1.2509	1.1606	1.0708	1.0092	13	13	13	12
1603	Pain syndrome M<26.75	1.5845	1.4703	1.3565	1.2784	14	17	16	15
1701	Major multiple trauma without brain or spinal cord injury M>39.25.	1.0432	0.9290	0.8566	0.7881	11	11	10	10
1702	Major multiple trauma without brain or spinal cord injury M>31.05 and M<39.25.	1.3109	1.1674	1.0764	0.9903	13	14	12	12
1703	Major multiple trauma without brain or spinal cord injury M>25.55 and M<31.05.	1.5378	1.3694	1.2627	1.1617	16	16	15	14
1704	Major multiple trauma without brain or spinal cord injury M<25.55.	1.9856	1.7682	1.6303	1.5000	20	20	18	17
1801	Major multiple trauma with brain or spinal cord injury M>40.85.	1.0662	0.9437	0.8082	0.7231	11	11	10	9

TABLE 1—RELATIVE WEIGHTS AND AVERAGE LENGTH OF STAY VALUES FOR CASE-MIX GROUPS—Continued

CMG	CMG description (M=motor, C=cognitive, A=age)	Relative weight				Average length of stay			
		Tier 1	Tier 2	Tier 3	None	Tier 1	Tier 2	Tier 3	None
1802	Major multiple trauma with brain or spinal cord injury M>23.05 and M<40.85.	1.6884	1.4945	1.2798	1.1451	17	16	15	14
1803	Major multiple trauma with brain or spinal cord injury M<23.05.	2.8097	2.4869	2.1297	1.9055	32	28	22	22
1901	Guillain Barre M>35.95	1.0421	0.9341	0.9263	0.8837	15	10	13	11
1902	Guillain Barre M>18.05 and M<35.95.	1.8757	1.6814	1.6672	1.5905	25	19	18	19
1903	Guillain Barre M<18.05	3.3752	3.0255	3.0000	2.8620	44	31	36	31
2001	Miscellaneous M>49.15	0.8827	0.7250	0.6681	0.6098	9	8	8	8
2002	Miscellaneous M>38.75 and M<49.15.	1.1872	0.9751	0.8986	0.8201	12	11	11	10
2003	Miscellaneous M>27.85 and M<38.75.	1.5061	1.2370	1.1400	1.0405	15	14	13	12
2004	Miscellaneous M<27.85	1.9507	1.6021	1.4765	1.3475	20	18	16	15
2101	Burns M>0	1.8405	1.6766	1.5548	1.3534	27	18	17	16
5001	Short-stay cases, length of stay is 3 days or fewer.				0.1549				2
5101	Expired, orthopedic, length of stay is 13 days or fewer.				0.6791				7
5102	Expired, orthopedic, length of stay is 14 days or more.				1.5539				16
5103	Expired, not orthopedic, length of stay is 15 days or fewer.				0.7274				8
5104	Expired, not orthopedic, length of stay is 16 days or more.				1.9477				21

Generally, updates to the CMG relative weights result in some increases and some decreases to the CMG relative weight values. Table 2 shows how we estimate that the application of the proposed revisions for FY 2015 would affect particular CMG relative weight

values, which would affect the overall distribution of payments within CMGs and tiers. Note that, because we propose to implement the CMG relative weight revisions in a budget-neutral manner (as described above), total estimated aggregate payments to IRFs for FY 2015

would not be affected as a result of the proposed CMG relative weight revisions. However, the revisions will affect the distribution of payments within CMGs and tiers.

TABLE 2—DISTRIBUTIONAL EFFECTS OF THE CHANGES TO THE CMG RELATIVE WEIGHTS
[FY 2014 values compared with FY 2015 values]

Percentage change	Number of cases affected	Percentage of cases affected
Increased by 15% or more	0	0.0
Increased by between 5% and 15%	1,023	0.3
Changed by less than 5%	382,960	99.4
Decreased by between 5% and 15%	1,288	0.3
Decreased by 15% or more	25	0.0

As Table 2 shows, more than 99 percent of all IRF cases are in CMGs and tiers that will experience less than a 5 percent change (either increase or decrease) in the CMG relative weight value as a result of the revisions for FY 2015. The largest estimated increase in the proposed CMG relative weight values that affects the largest number of IRF discharges is a 1.2 percent increase in the CMG relative weight value for CMG 0704—Fracture of lower extremity, with a motor score less than 28.15 in the

“no comorbidity” tier. In the FY 2013 claims data, 20,017 IRF discharges (5.2 percent of all IRF discharges) were classified into this CMG and tier.

The largest decrease in a CMG relative weight value affecting the largest number of IRF cases is a 0.8 percent decrease in the CMG relative weight for CMG 0604—Neurological, with a motor score less than 25.85 in the “no comorbidity” tier. In the FY 2013 IRF claims data, this change would have

affected 8,766 cases (2.3 percent of all IRF cases).

The changes in the average length of stay values for FY 2015, compared with the FY 2014 average length of stay values, are small and do not show any particular trends in IRF length of stay patterns.

We received 1 comment on the proposed update to the CMG relative weights and average length of stay values for FY 2015, which is summarized below.

Comment: The commenter requested that we provide more detail about the use of the CCR data in the CMG relative weight calculations. Additionally, the commenter requested that we outline the methodology used to calculate the average length of stay values in the IRF PPS rule.

Response: A key variable used to calculate the CMG relative weights is a facility's average cost per case, which is obtained by averaging the estimated cost per case for every patient discharged from the facility in a given fiscal year. To obtain the estimated cost per case for a given IRF patient, we start by pulling the appropriate charges from the Medicare claim for that patient. Then, we calculate the appropriate CCRs from the Medicare cost report submitted by the facility. The CCRs are then multiplied by the charges from the Medicare claim to obtain the estimated IRF cost for the case. This variable is used as the dependent variable in the regression analysis to estimate the CMG relative weights.

In conjunction with the publication of the IRF PPS FY 2014 final rule, we posted our methodology for calculating the average length of stay values on the IRF PPS Web site at <http://www.cms.gov/medicare-fee-for-service-payment/inpatientrehab/facpps/research.html>.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to update the CMG relative weight and average length of stay values for FY 2015. These updates are effective October 1, 2014.

V. Freezing the Facility-Level Adjustment Factors at FY 2014 Levels

A. Background on Facility-Level Adjustments

Section 1886(j)(3)(A)(v) of the Act confers broad authority upon the Secretary to adjust the per unit payment rate "by such . . . factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities." For example, we adjust the federal prospective payment amount associated with a CMG to account for facility-level characteristics such as an IRF's LIP, teaching status, and location in a rural area, if applicable, as described in § 412.624(e).

In the FY 2010 IRF PPS final rule (74 FR 39762), we updated the adjustment factors for calculating the rural, LIP, and teaching status adjustments based on the most recent three consecutive years' worth of IRF claims data (at that time, FY 2006, FY 2007, and FY 2008) and the most recent available corresponding IRF

cost report data. As discussed in the FY 2010 IRF PPS proposed rule (74 FR 21060 through 21061), we observed relatively large year-to-year fluctuations in the underlying data used to compute the adjustment factors, especially the teaching status adjustment factor. Therefore, we implemented a 3-year moving average approach to updating the facility-level adjustment factors in the FY 2010 IRF PPS final rule (74 FR 39762) to provide greater stability and predictability of Medicare payments for IRFs.

Each year, we review the major components of the IRF PPS to maintain and enhance the accuracy of the payment system. For FY 2010, we implemented a change to our methodology that was designed to decrease the IRF PPS volatility by using a 3-year moving average to calculate the facility-level adjustment factors. For FY 2011, we issued a notice to update the payment rates, which did not include any policy changes or changes to the IRF facility-level adjustments. As we found that the implementation of the 3-year moving average did not fully address year-to-year fluctuations, in the FY 2012 IRF PPS proposed rule (76 FR 24214, 24225 through 24226), we analyzed the effects of having used a weighting methodology. The methodology assigned greater weight to some facilities than to others in the regression analysis used to estimate the facility-level adjustment factors. As we found that this weighting methodology inappropriately exaggerated the cost differences among different types of IRF facilities, we proposed to remove the weighting factor from our analysis and update the IRF facility-level adjustment factors for FY 2012 using an unweighted regression analysis. However, after carefully considering all of the comments that we received on the proposed FY 2012 updates to the facility-level adjustment factors, we decided to hold the facility-level adjustment factors at FY 2011 levels for FY 2012 to conduct further research on the underlying data and the best methodology for calculating the facility-level adjustment factors. We based this decision, in part, on comments we received about the financial hardships that the proposed updates would create for facilities with teaching programs and a higher disproportionate share of low-income patients.

B. Freezing the Facility-Level Adjustment Factors at FY 2014 Levels

Since the FY 2012 final rule (76 FR 47836), we have conducted further research into the best methodology to use to estimate the IRF facility-level

adjustment factors, to ensure that the adjustment factors reflect as accurately as possible the costs of providing IRF care across the full spectrum of IRF providers. Our recent research efforts reflect the significant differences that exist between the cost structures of freestanding IRFs and the cost structures of IRF units of acute care hospitals (and critical access hospitals, otherwise known as "CAHs"). We have found that these cost structure differences substantially influence the estimates of the adjustment factors. Therefore, we believe that it is important to control for these cost structure differences between hospital-based and freestanding IRFs in our regression analysis, so that these differences do not inappropriately influence the adjustment factor estimates. In Medicare's payment system for the treatment of end-stage renal disease (ESRD), we already control for the cost structure differences between hospital-based and freestanding facilities in the regression analyses that are used to set payment rates. Also, we received comments from an IRF industry association on the FY 2012 IRF PPS proposed rule suggesting that the addition of this particular control variable to the model could improve the methodology for estimating the IRF facility-level adjustment factors.

Thus, in the FY 2014 IRF PPS proposed rule, we proposed to add an indicator variable to our 3-year moving average methodology for updating the IRF facility-level adjustments that would have an assigned value of "1" if the facility is a freestanding IRF hospital or would have an assigned value of "0" if the facility is an IRF unit of an acute care hospital (or CAH). Adding this variable to the regression analysis enables us to control for the differences in costs that are primarily due to the differences in cost structures between freestanding and hospital-based IRFs, so that those differences do not become inappropriately intertwined with our estimates of the differences in costs between rural and urban facilities, high-LIP percentage and low-LIP percentage facilities, and teaching and non-teaching facilities. Further, by including this variable in the regression analysis, we greatly improve our ability to predict an IRF's average cost per case (that is, the R-squared of the regression model increases from about 11 percent to about 41 percent). In this way, it enhances the precision with which we can estimate the IRF facility-level adjustments.

In the FY 2014 IRF PPS final rule (78 FR 47860), we finalized our decision to add an indicator variable for a facility's freestanding/hospital-based status to the payment regression, and, with that

change, to update the IRF facility-level adjustment factors for FY 2014 using the same methodology, with the exception of adding the indicator variable, that we used in updating the FY 2010 IRF facility-level adjustment factors, including the 3-year moving average approach. Thus, in the FY 2014 IRF PPS final rule, we finalized a rural adjustment of 14.9 percent, a LIP adjustment factor of 0.3177, and a teaching status adjustment factor of 1.0163 for FY 2014.

Based on the substantive changes to the facility-level adjustment factors that were adopted in the FY 2014 final rule, we are freezing the facility-level adjustment factors for FY 2015 and all subsequent years at the FY 2014 levels while we continue to monitor the most current IRF claims data available and evaluate the effects of the FY 2014 changes. Additionally, we want to allow providers time to acclimate to the FY 2014 changes. At such future time as our data analysis may indicate the need for further updates to the facility-level adjustment factors, we would propose to update the adjustment factors through notice and comment rulemaking.

We received 4 comments on our proposal to freeze the facility-level adjustment factors at FY 2014 levels for FY 2015 and all subsequent years (unless and until we propose to update them again through future notice and comment rulemaking), which are summarized below.

Comment: The majority of commenters support our proposal to freeze the facility-level adjustment factors. However, those same commenters encourage CMS to continue to analyze changes to the facility-level adjustments and adjust all three factors at a minimum of every three years. Additionally, commenters recommended that CMS make the methodology and findings available to the public.

Response: We appreciate the commenters' support with our decision to freeze the facility-level adjustment factors. As discussed in the proposed rule, we believe that it is appropriate to freeze the facility-level adjustment factors at FY 2014 levels while we continue to monitor the most current IRF claims data available and evaluate the effects of the FY 2014 changes. Additionally, this will allow providers time to acclimate to the FY 2014 changes that were implemented. We will continue to monitor the data and periodically update the adjustment factors, as needed, to ensure the accuracy of IRF PPS payment rates. Rather than specify an exact period, such as every 3 years, for updating the

adjustment factors, we believe that it is better for the overall efficiency of the IRF PPS payment system to update the adjustment factors whenever it appears that the benefits of updating (in terms of improved accuracy of payment rates) outweigh the costs (in terms of less stability in the annual payment rates). At such time as we determine that the data support updating the adjustment factors or changes in the methodology, we will make our findings available through the rulemaking process.

Comment: One commenter suggested that CMS be more transparent about the criteria the agency is using to determine when changes to the facility-level adjustments occur. For example, the commenter suggested CMS adopt a minimum threshold of annual change for the adjustment factors, such as 5 to 10 percent and examine unfreezing the adjustment factors and issuing an update if analysis finds that any of the factors meet or exceed the suggested threshold.

Response: While we agree with transparency during this process, we do not believe that setting a minimum threshold of annual change would be beneficial to the industry or to the Medicare program. As stated in our previous response, we believe that monitoring the data and making periodic changes when the benefits of such changes outweigh the costs is the most appropriate way to enhance both the accuracy and the stability of the IRF PPS payment system. In addition, we disagree with the suggestion that we should publicize the interim results that we use in making these determinations each time. We believe that this would only serve to confuse the industry, as the adjustment factors tend to fluctuate significantly from one period to the next and providers would potentially be confused about which adjustment factors were being proposed for implementation and which ones were not.

Comment: One commenter suggested that depending on the magnitude of any change in facility level adjustments, CMS should also propose a transition to phase in the implementation.

Response: Thank you for your comment. We will certainly take this recommendation into consideration for the future.

Final Decision: After careful consideration of the public comments, we are finalizing our proposal to freeze the facility-level adjustment factors for FY 2015 and all subsequent years (unless and until we propose to update them again through future notice and comment rulemaking).

VI. FY 2015 IRF PPS Federal Prospective Payment Rates

A. Market Basket Increase Factor, Productivity Adjustment, and Other Adjustment for FY 2015

Section 1886(j)(3)(C) of the Act requires the Secretary to establish an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services, which is referred to as a market basket index. According to section 1886(j)(3)(A)(i) of the Act, the increase factor shall be used to update the IRF federal prospective payment rates for each FY. Sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act required the application of a 0.2 percentage point reduction to the market basket increase factor for FY 2015. In addition, section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment, as described below. Thus, in the FY 2015 IRF PPS proposed rule, we proposed to update the IRF PPS payments for FY 2015 by a market basket increase factor based upon the most current data available, with a productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, as described below and a 0.2 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act.

For this final rule, we use the same methodology described in the FY 2012 IRF PPS final rule (76 FR 47836 at 47848 through 47863) to compute the FY 2015 market basket increase factor and labor-related share. In that final rule, we described the market basket (referred to as the RPL market basket) as reflecting a FY 2008 base year. Based on IHS Global Insight's second quarter 2014 forecast, the most recent estimate of the 2008-based RPL market basket increase factor for FY 2015 is 2.9 percent. IHS Global Insight (IGI) is an economic and financial forecasting firm that contracts with CMS to forecast the components of providers' market baskets.

In accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and using the methodology described in the FY 2012 IRF PPS final rule (76 FR 47836, 47858 through 47859), we apply a productivity adjustment to the FY 2015 RPL market basket increase factor. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY cost reporting period, or other

annual period) (the “MFP adjustment”). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. We refer readers to the BLS Web site at <http://www.bls.gov/mfp> to obtain the historical BLS-published MFP data. The projection of MFP is currently produced by IGI, using the methodology described in the FY 2012 IRF PPS final rule (76 FR 47836, 47859). The most recent estimate of the MFP adjustment for FY 2015 (the 10-year moving average of MFP for the period ending FY 2015) is 0.5 percent, which was calculated using the methodology described in the FY 2012 IRF PPS final rule (76 FR 47836, 47858 through 47859) and is based on IGI’s second quarter 2014 forecast.

Thus, in accordance with section 1886(j)(3)(C) of the Act, we base the FY 2015 market basket update, which is used to determine the applicable percentage increase for the IRF payments, on the most recent estimate of the FY 2008-based RPL market basket (currently estimated to be 2.9 percent based on IGI’s second quarter 2014 forecast). We then reduce this percentage increase by the current estimate of the MFP adjustment for FY 2015 of 0.5 percentage point (the 10-year moving average of MFP for the period ending FY 2015 based on IGI’s second quarter 2014 forecast), which was calculated as described in the FY 2012 IRF PPS final rule (76 FR 47836, 47859). Following application of the MFP, we further reduce the applicable percentage increase by 0.2 percentage point, as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act. Therefore, the current estimate of the FY 2015 IRF update is 2.2 percent (2.9 percent market basket update, less 0.5 percentage point MFP adjustment, less 0.2 percentage point legislative adjustment).

We received 5 comments on the proposed market basket increase factor, which are summarized below.

Comment: While several commenters supported the update to IRF payment rates for FY 2015, one commenter stated that the update to the IRF payment rates is not warranted based on the review of many factors—including indicators of beneficiary access to rehabilitative services, the supply of providers, and Medicare margins. The commenter said that Medicare’s current payment rates for IRFs appear to be adequate and, therefore, recommended no update to IRF payment rates for FY 2015.

Response: We are finalizing the IRF PPS payment update for FY 2015 of 2.2 percent (2.9 percent market basket update, less 0.5 percentage point MFP

adjustment, less 0.2 percentage point legislative adjustment), as section 1886(j)(3)(C) of the Act does not provide the Secretary with the authority to apply a different update factor to IRF PPS payment rates for FY 2015.

Comment: Several commenters expressed concern about the applicability of the productivity adjustment to the IRF setting. One commenter suggested that we take into consideration the unique needs of rehabilitation patients and the highly skilled professional teams who provide their care. This commenter also stated that CMS should be mindful that increasing reimbursement financial pressures without allowing IRFs to improve their efficiency in ways that best serve patients may result in barriers to access for the most complex and needy Medicare beneficiaries. Another commenter noted that while CMS is bound by the Affordable Care Act to apply specific market basket reductions to the full market basket update in FY 2015 and subsequent years, they believe it is unlikely that productivity improvements will be generated by rehabilitation hospitals at a pace matching the productivity of the economy at large on an ongoing, consistent basis. The commenter also noted that services provided in rehabilitation hospitals are very labor intensive through the provision of hands-on care by physical therapists, occupational therapists, speech therapists and rehabilitation nursing staff, and that many of the treatment plans do not lend themselves to continual productivity improvements. The commenter said that we should carefully monitor the impact that the productivity adjustments have on IRFs and provide feedback to Congress as appropriate.

Response: Section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment that must be applied to the IRF PPS market basket update. We will continue to monitor the impact of the payment updates, including the effects of the productivity adjustment, on IRF provider margins as well as beneficiary access to care.

Final Decision: Based on careful consideration of the comments, we are finalizing the FY 2015 market basket update for IRF payments of 2.2 percent, which is the most recent estimate of the FY 2008-based RPL market basket adjusted for productivity and the FY15 legislative reduction. Therefore, the current estimate of the FY 2015 IRF update is 2.2 percent (2.9 percent market basket update, less 0.5 percentage point MFP adjustment, less

0.2 percentage point legislative adjustment).

B. Development of an IRF-Specific Market Basket

In the FY 2010 IRF PPS proposed rule (74 FR 21062), we expressed our interest in exploring the possibility of creating a stand-alone, or IRF-specific, market basket that reflects the cost structures of only IRF providers. We noted that, of the available options, one would be to join the Medicare cost report data from freestanding IRF providers with data from hospital-based IRF providers. We indicated that an examination of the Medicare cost report data comparing freestanding and hospital-based IRFs revealed considerable differences between the two for cost levels and cost structures. At that time, we stated that we were unable to fully explain the differences in costs between freestanding and hospital-based IRFs and solicited comments regarding our findings. We summarized and responded to several public comments we received on the potential creation of a stand-alone IRF market basket in the FY 2010 IRF final rule (74 FR 39776 through 39778). At that time, we stated the need for further research regarding the differences in cost levels and cost structures between freestanding IRFs and hospital-based IRFs.

Since the FY 2010 IRF PPS final rule was published, we have made significant progress on the development of a stand-alone, or IRF-specific, market basket. Our research has focused on addressing several concerns regarding the use of the hospital-based IRF Medicare cost report data in the calculation of the major market basket cost weights. As discussed above, one concern is the cost level differences for hospital-based IRFs relative to freestanding IRFs that were not readily explained by the specific characteristics of the individual providers and the patients that they serve (for example, characteristics related to case mix, urban/rural status, teaching status). Furthermore, we are concerned about the variability in the cost report data among these hospital-based IRF providers and the potential impact on the market basket cost weights. These concerns led us to consider whether it is appropriate to use the universe of IRF providers to derive an IRF-specific market basket.

Recently, we have investigated the use of regression analysis to evaluate the effect of including hospital-based IRF Medicare cost report data in the calculation of cost distributions. We created preliminary regression models to try to explain variations in costs per

discharge across both freestanding and hospital-based IRFs. These models were intended to capture the effects of facility-level and patient-level characteristics (for example, wage index, urban/rural status, ownership status, length-of-stay, occupancy rate, case mix, and Medicare utilization) on IRF costs per discharge. Using the results from the preliminary regression analyses, we identified smaller subsets of hospital-based and freestanding IRF providers where the predicted costs per discharge using the regression model closely matched the actual costs per discharge for each IRF. We then derived different sets of cost distributions using (1) these subsets of IRF providers and (2) the entire universe of freestanding and hospital-based IRF providers (including those IRFs for which the variability in cost levels remains unexplained). After comparing these sets of cost distributions, the differences were not substantial enough for us to conclude that the inclusion of those IRF providers with unexplained variability in costs in the calculation of the cost distributions is a major cause of concern.

Another concern with incorporating the hospital-based IRF data in the derivation of an IRF-specific market basket is the complexity of the Medicare cost report data for these providers. The freestanding IRFs independently submit a Medicare cost report for their facilities, making it relatively straightforward to obtain the cost categories necessary to determine the major market basket cost weights. However, cost report data submitted for a hospital-based IRF are embedded in the Medicare cost report submitted for the entire hospital facility in which the IRF is located. Therefore, adjustments would have to be made to obtain cost weights that represent just the hospital-based IRF (as opposed to the hospital as a whole). For example, ancillary costs for services such as therapy, radiology, and laboratory services for the entire hospital would need to be appropriately converted to a value that only represents the hospital-based IRF unit's costs. The preliminary method we have developed to allocate these costs is complex and still needs to be fully evaluated before we are ready to propose an IRF-specific market basket that would reflect both hospital-based and freestanding IRF data.

In our ongoing research, we are also evaluating the differences in salary costs as a percent of total costs for both hospital-based and freestanding IRFs. Salary costs are historically the largest component of the market baskets. Based on our review of the data reported on

the applicable Medicare cost reports, our initial findings (using the preliminary allocation method as discussed above) have shown that the hospital-based IRF salary costs as a percent of total costs tend to be lower than those of freestanding IRFs. We are still evaluating the method for deriving salary costs as a percent of total costs, and one of the main issues is to further investigate the percentage of ancillary costs that should be appropriately allocated to the IRF salary costs for the hospital-based IRF, as discussed above.

Also, as stated in the FY 2012 IRF PPS final rule (76 FR 47836, 47851), effective for cost reports beginning on or after May 1, 2010, we finalized a revised Hospital and Hospital Health Care Complex Cost Report, Form CMS 2552–10 (74 FR 31738). The report is available for download from the CMS Web site at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Cost-Reports/Hospital-2010-form.html>. The revised Hospital and Hospital Health Care Complex Cost Report includes a new worksheet (Worksheet S–3, part V) that identifies the contract labor costs and benefit costs for the hospital/hospital care complex, is applicable to sub-providers and units. As we gain access to the data reported by IRFs on this new form, we plan to evaluate the appropriateness of using these data to derive benefits and contract labor cost weights for the market basket instead of the data and methods currently used for the RPL market basket. This includes comparing these data with costs submitted on the other forms composing the Medicare cost report.

For the reasons discussed above, while we believe we have made significant progress on the development of an IRF-specific market basket, we believe that further research is required at this time. As a result, we did not propose an IRF-specific market basket for FY 2015. We plan to complete our research during the remainder of this year and, provided that we are prepared to draw conclusions from our research, may propose an IRF-specific market basket for the FY 2016 rulemaking cycle.

We received 4 comments on the development of an IRF-specific market basket, which are summarized below.

Comment: One commenter agreed with the continued use of the RPL market basket instead of changing to a rehabilitation-specific market basket. The commenter noted that CMS has utilized the RPL Market Basket for several years and that CMS has not been able to reconcile the cost structure issues between freestanding and hospital-based rehabilitation facilities.

The commenter stated that CMS's description of attempts to adjust and convert costs and data from the hospital cost report for the hospital-based rehabilitation units will not ultimately reflect the true cost of that hospital-based unit, as it will be artificially derived based on assumptions and comparisons to freestanding rehabilitation facilities. Further, the commenter stated, the hospital-based rehabilitation unit is part of a higher cost structure facility, and any future rehabilitation market basket should reflect that.

Response: We have made significant progress in addressing our initial concerns of the research that showed substantial cost differences between hospital-based and freestanding IRF providers. Nonetheless, we concur with the commenter's concerns about the difficulty of disentangling cost of hospital-based IRFs from the overall hospital. We note that our regression analysis, detailed above, provides a start at addressing these issues. However, we disagree with the commenter's claim that data from hospital-based providers will not reflect the true cost of the hospital-based unit. We believe that the approach described above, while more complicated than only using freestanding facility cost report data, would directly reflect the costs of the hospital-based unit and be a technical improvement. As noted above, we will continue to research and analyze the development of an IRF-specific market basket that uses the most appropriate and reliable data sources and methods and provide detailed explanations of the proposed methodology most likely in the FY 2016 proposed rule.

Comment: Several commenters supported the proposal to have a stand-alone IRF market basket, but urged CMS to share findings and materials in a transparent manner in order to allow the IRF community to validate and analyze these research activities.

Response: As the commenters suggested, we will continue to research and analyze the development of an IRF-specific market basket that uses the most appropriate and reliable data sources and methods. We anticipate proposing to use an IRF-specific market basket in the FY 2016 IRF proposed rule, and the public will have the opportunity to comment on our market basket methodology and data sources during the 60-day comment period following the publication of the proposed rule.

Final Decision: After careful consideration of the comments, we will continue to research the possibility of creating and proposing an IRF-specific

market basket based on data from both freestanding and hospital-based IRF facilities in the future.

C. Secretary's Final Recommendation

For FY 2015, the Medicare Payment Advisory Commission (MedPAC) recommends that a 0.0 percent update be applied to IRF PPS payment rates. As discussed above, and in accordance with sections 1886(j)(3)(C) and 1886(j)(3)(D) of the Act, the Secretary proposes to update IRF PPS payment rates for FY 2015 by an adjusted market basket increase factor of 2.2 percent, as section 1886(j)(3)(C) of the Act does not provide the Secretary with the authority to apply a different update factor to IRF PPS payment rates for FY 2015.

We did not receive any public comments on the Secretary's recommendation.

D. Labor-Related Share for FY 2015

The labor-related share for FY 2015 is updated using the methodology described in the FY 2012 IRF PPS final rule (76 FR 47836, 47860 through 47863). Using this method and IGI's second quarter 2014 forecast of the 2008-based RPL market basket, the proposed IRF labor-related share for FY 2015 is the sum of the FY 2015 relative importance of each labor-related cost category. This figure reflects the different rates of price change for these cost categories between the base year (FY 2008) and FY 2015. As shown in Table 3, the FY 2015 labor-related share is 69.294 percent.

TABLE 3—FY 2015 IRF RPL LABOR-RELATED SHARE RELATIVE IMPORTANCE

	FY 2015 Relative importance labor- related share
Wages and Salaries	48.271
Employee Benefits	12.963
Professional Fees: Labor- Related	2.058
Administrative and Business Support Services	0.415
All Other: Labor-Related Services	2.061
Subtotal	65.741
Labor-Related Portion of Capital Costs (.46)	3.553
Total Labor-Related Share	69.294

Source: IHS Global Insight, Inc. Second quarter 2014 forecast; Historical Data through 1st quarter 2014.

We received one comment on the proposed IRF labor-related share for FY 2015, which is summarized below.

Comment: One commenter supported using the latest available data to update the IRF PPS and noted that the current methodology relies upon acute care hospital data for certain items (that is, employee benefits, contract labor) that were not collected in RPL settings. The commenter also noted that changes to the Medicare cost report (Form 2552–10) were implemented to gather additional information on labor costs. The commenter requested that CMS continue to review the available data and, if appropriate, implement changes to allow the use of IRF-specific data for all cost categories, weights and price proxies.

Response: We appreciate the commenter's concerns with respect to the data for the benefits and contract labor categories. We have been monitoring and analyzing the data that is being reported based on the revised cost report and instructions. We hope to use this data in the future if it is statistically representative and we have a reliable response rate for these data.

Final Decision: After careful consideration of the comments, we are finalizing the FY 2015 labor-related share of 69.294 percent.

E. Wage Adjustment

Section 1886(j)(6) of the Act requires the Secretary to adjust the proportion of rehabilitation facilities' costs attributable to wages and wage-related costs (as estimated by the Secretary from time to time) by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for those facilities. The Secretary is required to update the IRF PPS wage index on the basis of information available to the Secretary on the wages and wage-related costs to furnish rehabilitation services. Any adjustment or updates made under section 1886(j)(6) of the Act for a FY are made in a budget-neutral manner.

For FY 2015, we are maintaining the policies and methodologies described in the FY 2012 IRF PPS final rule (76 FR 47836, at 47863 through 47865) related to the labor market area definitions and the wage index methodology for areas with wage data. Thus, we are using the CBSA labor market area definitions and the FY 2014 pre-reclassification and pre-floor hospital wage index data. In accordance with section 1886(d)(3)(E) of the Act, the FY 2014 pre-reclassification and pre-floor hospital wage index is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2009, and before

October 1, 2010 (that is, FY 2010 cost report data).

The labor market designations made by the OMB include some geographic areas where there are no hospitals and, thus, no hospital wage index data on which to base the calculation of the IRF PPS wage index. We will continue to use the same methodology discussed in the FY 2008 IRF PPS final rule (72 FR 44299) to address those geographic areas where there are no hospitals and, thus, no hospital wage index data on which to base the calculation for the FY 2015 IRF PPS wage index.

In accordance with our established methodology, we have historically adopted any CBSA changes that are published in the OMB bulletin that corresponds with the hospital wage data used to determine the IRF PPS wage index. The OMB bulletins are available at <http://www.whitehouse.gov/omb/bulletins/index.html>.

In keeping with the established IRF PPS wage index policy; we will use the prior year's (FY 2014) pre-floor, pre-reclassified hospital wage index data to derive the FY 2015 applicable IRF PPS wage index. We anticipate using the FY 2014 pre-floor, pre-reclassified hospital wage index data to derive the applicable IRF PPS wage index for FY 2015. We note, however, that the FY 2014 pre-floor, pre-reclassified hospital wage index does not use OMB's new 2010 Census-based area delineations, which were outlined in the February 28, 2013, OMB Bulletin 13–01, as we did not receive these changes in time to incorporate them into the FY 2014 hospital wage index. We therefore intend to consider the incorporation of these CBSA changes during the development of the FY 2015 hospital wage index. Assuming that we would continue to follow our established methodology for the IRF PPS wage index, this means that the 2010 Census-based CBSA changes would not be considered for inclusion in the IRF PPS wage index until FY 2016.

To calculate the wage-adjusted facility payment for the payment rates set forth in this final rule, we multiply the unadjusted Federal payment rate for IRFs by the FY 2015 labor-related share based on the FY 2008-based RPL market basket (69.294 percent) to determine the labor-related portion of the standard payment amount. We then multiply the labor-related portion by the applicable IRF wage index from the tables in the addendum to this final rule. These tables are available through the Internet on the CMS Web site at <http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/>. Table A is for

urban areas, and Table B is for rural areas.

Adjustments or updates to the IRF wage index made under section 1886(j)(6) of the Act must be made in a budget-neutral manner. We calculate a budget-neutral wage adjustment factor as established in the FY 2004 IRF PPS final rule (68 FR 45689), codified at § 412.624(e)(1), as described in the steps below. We use the listed steps to ensure that the FY 2015 IRF standard payment conversion factor reflects the update to the wage indexes (based on the FY 2010 hospital cost report data) and the labor-related share in a budget-neutral manner:

Step 1. Determine the total amount of the estimated FY 2014 IRF PPS rates, using the FY 2014 standard payment conversion factor and the labor-related share and the wage indexes from FY 2014 (as published in the FY 2014 IRF PPS final rule (78 FR 47860)).

Step 2. Calculate the total amount of estimated IRF PPS payments using the FY 2015 standard payment conversion factor and the FY 2015 labor-related share and CBSA urban and rural wage indexes.

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the FY 2015 budget-neutral wage adjustment factor of 1.0017.

Step 4. Apply the FY 2015 budget-neutral wage adjustment factor from step 3 to the FY 2014 IRF PPS standard payment conversion factor after the application of the adjusted market basket update to determine the FY 2015 standard payment conversion factor.

We discuss the calculation of the standard payment conversion factor for FY 2015 in section VI.F. of this final rule.

We received 4 comments on the proposed IRF wage adjustment for FY 2015, which are summarized below.

Comment: Several commenters expressed concern regarding the possible incorporation of the 2010 Census-based CBSA changes in the calculation of the wage index and the time frame over which the changes would be implemented. More specifically, these commenters urged CMS to establish a two-year or four-year phase-in for the wage index changes, particularly for providers most adversely affected by the new CBSA delineations.

Response: We appreciate all of the comments on this topic and support for the proposed FY 2015 wage index methodology. We will take these comments into consideration during the development of the FY 2016 IRF PPS wage index.

Comment: Commenters recommended that we develop a new methodology for area wage adjustment that eliminates hospital wage index reclassifications for all hospitals and reduces the problems associated with annual fluctuations in wage indices and across geographic boundaries. These commenters also recommended that we consider wage index policies under the current IPPS because IRFs compete in a similar labor pool as acute care hospitals. The commenters suggested that the IPPS wage index policies would allow IRFs to benefit from the IPPS reclassification and/or floor policies. One commenter further recommended that until a new wage index system is implemented, we institute a “smoothing” variable to the current process to reduce the fluctuations IRFs annually experience.

Response: Consistent with our previous responses to these comments (most recently published in our FY 2014 IRF PPS final rule (78 FR 47874)), we note that the IRF PPS does not account for geographic reclassification under sections 1886(d)(8) and (d)(10) of the Act, and does not apply the “rural floor” under section 4410 of the BBA. Furthermore, as we do not have an IRF-specific wage index, we are unable to determine at this time the degree, if any, to which a geographic reclassification adjustment or a “rural floor” policy under the IRF PPS would be appropriate. The rationale for our current wage index policies is fully described in the FY 2006 IRF PPS final rule (70 FR 47880, 47926 through 47928).

Additionally, while some commenters recommended that we adopt IPPS reclassification and/or floor policies, we note the Medicare Payment Advisory Commission (MedPAC’s) June 2007 report to the Congress, titled “Report to Congress: Promoting Greater Efficiency in Medicare,” (available at http://www.medpac.gov/documents/Jun07_EntireReport.pdf) recommends that Congress “repeal the existing hospital wage index statute, including reclassification and exceptions, and give the Secretary authority to establish new wage index systems.” We continue to believe it would not be prudent at this time to adopt the IPPS wage index policies, such as reclassification and/or floor policies, and will, therefore, continue to use the CBSA labor market area definitions and the pre-reclassification and pre-floor hospital wage index data based on 2010 cost report data in this final rule.

With regard to issues mentioned about ensuring that the wage index minimizes fluctuations, matches the costs of labor in the market, and

provides for a single wage index policy, section 3137(b) of the Affordable Care Act required us to submit a report to the Congress by December 31, 2011 that includes a plan to reform the hospital wage index system. The report that we submitted is available online at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html>.

However, we will continue to monitor the IPPS wage index to identify any policy changes that may be appropriate for IRFs. This is consistent with our previous responses to these recurring comments.

Final Decision: After careful consideration of the comments, we are finalizing use of the FY 2014 pre-floor, pre-reclassified hospital wage index data to derive the applicable IRF PPS wage index for FY 2015.

F. Description of the IRF Standard Conversion Factor and Payment Rates for FY 2015

To calculate the standard payment conversion factor for FY 2015, as illustrated in Table 4, we begin by applying the adjusted market basket increase factor for FY 2015 that was adjusted in accordance with sections 1886(j)(3)(C) and (D) of the Act, to the standard payment conversion factor for FY 2014 (\$14,846). Applying the 2.2 percent adjusted market basket increase factor for FY 2015 to the standard payment conversion factor for FY 2014 of \$14,846 yields a standard payment amount of \$15,173. Then, we apply the budget neutrality factor for the FY 2015 wage index and labor-related share of 1.0017, which results in a standard payment amount of \$15,198. We next apply the budget neutrality factors for the revised CMG relative weights of 1.0000, which results in the proposed standard payment conversion factor of \$15,198 for FY 2015.

TABLE 4—CALCULATIONS TO DETERMINE THE FY 2015 STANDARD PAYMENT CONVERSION FACTOR

Explanation for adjustment	Calculations
Standard Payment Conversion Factor for FY 2014	\$14,846
Market Basket Increase Factor for FY 2015 (2.9 percent), reduced by a 0.5 percentage point reduction for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, and reduced by 0.2 percentage points in accordance with paragraphs 1886(j)(3)(C) and (D) of the Act	× 1.0220

TABLE 4—CALCULATIONS TO DETERMINE THE FY 2015 STANDARD PAYMENT CONVERSION FACTOR—Continued

Explanation for adjustment	Calculations
Budget Neutrality Factor for the Wage Index and Labor-Related Share	× 1.0017
Budget Neutrality Factor for the Revisions to the CMG Relative Weights	× 1.0000

TABLE 4—CALCULATIONS TO DETERMINE THE FY 2015 STANDARD PAYMENT CONVERSION FACTOR—Continued

Explanation for adjustment	Calculations
FY 2015 Standard Payment Conversion Factor	= \$15,198
We did not receive any comments on the proposed FY 2015 standard payment conversion factor.	

Final Decision: As we did not receive any comments on the proposed FY 2015 standard payment conversion factor, we are finalizing the IRF standard payment conversion factor at \$15,198 for FY 2015.

After the application of the CMG relative weights described in section IV of this final rule, to the FY 2015 standard payment conversion factor (\$15,198), the resulting unadjusted IRF prospective payment rates for FY 2015 are shown in Table 5.

TABLE 5—FY 2015 PAYMENT RATES

CMG	Payment rate Tier 1	Payment rate Tier 2	Payment rate Tier 3	Payment rate no comorbidity
0101	\$11,934.99	\$10,866.57	\$9,896.94	\$9,495.71
0102	14,948.75	13,609.81	12,393.97	11,893.95
0103	17,684.39	16,100.76	14,663.03	14,070.31
0104	18,421.50	16,772.51	15,273.99	14,656.95
0105	21,512.77	19,587.18	17,837.89	17,115.99
0106	24,521.97	22,327.38	20,333.40	19,511.19
0107	27,395.91	24,942.96	22,714.93	21,796.97
0108	34,145.35	31,089.03	28,312.35	27,167.94
0109	31,262.29	28,462.81	25,920.19	24,873.05
0110	40,925.17	37,262.46	33,934.09	32,561.72
0201	12,378.77	10,085.39	9,048.89	8,632.46
0202	16,096.20	13,114.35	11,764.77	11,223.72
0203	18,483.81	15,059.70	13,511.02	12,889.42
0204	20,360.76	16,588.62	14,883.40	14,197.97
0205	24,201.30	19,717.89	17,690.47	16,875.86
0206	29,373.17	23,932.29	21,470.21	20,482.34
0207	38,967.67	31,748.62	28,482.57	27,174.02
0301	16,751.24	14,170.62	12,846.87	11,851.40
0302	20,971.72	17,740.63	16,082.52	14,836.29
0303	24,880.65	21,047.71	19,081.09	17,603.84
0304	32,738.01	27,693.80	25,107.10	23,161.75
0401	15,599.23	13,359.04	12,357.49	11,020.07
0402	21,441.34	18,360.70	16,985.28	15,146.33
0403	35,045.07	30,011.49	27,763.71	24,756.02
0404	62,056.47	53,142.85	49,162.49	43,838.63
0405	50,692.93	43,411.57	40,160.72	35,811.05
0501	12,793.68	10,340.72	9,478.99	8,576.23
0502	17,599.28	14,223.81	13,038.36	11,798.21
0503	21,844.09	17,654.00	16,182.83	14,643.27
0504	25,737.81	20,801.50	19,067.41	17,252.77
0505	29,430.93	23,786.39	21,803.05	19,728.52
0506	41,134.91	33,245.63	30,475.03	27,575.25
0601	15,643.30	12,384.85	11,438.01	10,428.87
0602	20,187.50	15,982.22	14,761.82	13,459.35
0603	25,421.69	20,126.71	18,588.67	16,948.81
0604	33,295.78	26,360.93	24,347.20	22,199.72
0701	14,742.06	12,249.59	11,743.49	10,693.31
0702	18,889.59	15,694.97	15,047.54	13,702.52
0703	22,882.11	19,014.22	18,228.48	16,599.26
0704	29,421.81	24,447.50	23,436.84	21,344.07
0801	11,249.56	9,222.15	8,523.04	7,860.41
0802	15,032.34	12,324.06	11,390.90	10,504.86
0803	20,325.81	16,661.57	15,400.13	14,202.53
0804	17,965.56	14,726.86	13,611.33	12,553.55
0805	22,344.10	18,318.15	16,930.57	15,614.43
0806	26,844.23	22,005.18	20,339.48	18,757.37
0901	14,264.84	11,521.60	10,743.47	9,714.56
0902	18,818.16	15,198.00	14,172.14	12,814.95
0903	23,635.93	19,090.21	17,801.42	16,096.20
0904	30,049.49	24,268.17	22,629.82	20,462.59
1001	15,538.44	14,134.14	12,241.99	11,193.33
1002	20,012.73	18,204.16	15,766.41	14,415.30
1003	28,538.80	25,959.70	22,483.92	20,558.33
1101	19,214.83	15,415.33	15,273.99	13,023.17
1102	28,778.93	23,088.80	22,876.03	19,506.63
1201	15,249.67	14,471.54	13,497.34	12,547.47

TABLE 5—FY 2015 PAYMENT RATES—Continued

CMG	Payment rate Tier 1	Payment rate Tier 2	Payment rate Tier 3	Payment rate no comorbidity
1202	18,109.94	17,185.90	16,029.33	14,901.64
1203	22,999.13	21,824.33	20,354.68	18,924.55
1301	18,571.96	15,026.26	13,187.30	12,433.48
1302	24,184.58	19,565.91	17,172.22	16,190.43
1303	30,854.98	24,962.72	21,909.44	20,655.60
1401	13,726.83	11,131.02	10,138.59	9,196.31
1402	18,157.05	14,725.34	13,412.24	12,164.48
1403	22,339.54	18,116.02	16,500.47	14,965.47
1404	28,105.66	22,793.96	20,760.47	18,830.32
1501	15,194.96	12,386.37	11,454.73	11,068.70
1502	19,736.12	16,088.60	14,880.36	14,378.83
1503	24,192.18	19,720.92	18,239.12	17,625.12
1504	29,921.82	24,391.27	22,558.39	21,798.49
1601	14,354.51	13,318.01	12,287.58	11,580.88
1602	19,011.18	17,638.80	16,274.02	15,337.82
1603	24,081.23	22,345.62	20,616.09	19,429.12
1701	15,854.55	14,118.94	13,018.61	11,977.54
1702	19,923.06	17,742.15	16,359.13	15,050.58
1703	23,371.48	20,812.14	19,190.51	17,655.52
1704	30,177.15	26,873.10	24,777.30	22,797.00
1801	16,204.11	14,342.35	12,283.02	10,989.67
1802	25,660.30	22,713.41	19,450.40	17,403.23
1803	42,701.82	37,795.91	32,367.18	28,959.79
1901	15,837.84	14,196.45	14,077.91	13,430.47
1902	28,506.89	25,553.92	25,338.11	24,172.42
1903	51,296.29	45,981.55	45,594.00	43,496.68
2001	13,415.27	11,018.55	10,153.78	9,267.74
2002	18,043.07	14,819.57	13,656.92	12,463.88
2003	22,889.71	18,799.93	17,325.72	15,813.52
2004	29,646.74	24,348.72	22,439.85	20,479.31
2101	27,971.92	25,480.97	23,629.85	20,568.97
5001				2,354.17
5101				10,320.96
5102				23,616.17
5103				11,055.03
5104				29,601.14

G. Example of the Methodology for Adjusting the Federal Prospective Payment Rates

Table 6 illustrates the methodology for adjusting the federal prospective payments (as described in sections VI.A. through VI.F. of this final rule). The following examples are based on two hypothetical Medicare beneficiaries, both classified into CMG 0110 (without comorbidities). The unadjusted federal prospective payment rate for CMG 0110 (without comorbidities) appears in Table 6.

Example: One beneficiary is in Facility A, an IRF located in rural Spencer County, Indiana, and another beneficiary is in Facility B, an IRF located in urban Harrison County, Indiana. Facility A, a rural non-teaching hospital has a Disproportionate Share Hospital (DSH) percentage of 5 percent (which would result in a LIP adjustment of 1.0156), a wage index of 0.8513, and a rural adjustment of 14.9 percent. Facility B, an urban teaching hospital,

has a DSH percentage of 15 percent (which would result in a LIP adjustment of 1.0454 percent), a wage index of 0.8852, and a teaching status adjustment of 0.0784.

To calculate each IRF's labor and non-labor portion of the Federal prospective payment, we begin by taking the unadjusted Federal prospective payment rate for CMG 0110 (without comorbidities) from Table 5. Then, we multiply the labor-related share for FY 2015 (69.294 percent) described in section VI.D. of this final rule by the unadjusted federal prospective payment rate. To determine the non-labor portion of the federal prospective payment rate, we subtract the labor portion of the federal payment from the unadjusted federal prospective payment.

To compute the wage-adjusted federal prospective payment, we multiply the labor portion of the federal payment by the appropriate wage index found in tables A and B. These tables are available through the Internet on the CMS Web site at [http://](http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/Inpatient-RehabFacPPS/)

www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/Inpatient-RehabFacPPS/. The resulting figure is the wage-adjusted labor amount. Next, we compute the wage-adjusted federal payment by adding the wage-adjusted labor amount to the non-labor portion.

Adjusting the wage-adjusted federal payment by the facility-level adjustments involves several steps. First, we take the wage-adjusted Federal prospective payment and multiply it by the appropriate rural and LIP adjustments (if applicable). Second, to determine the appropriate amount of additional payment for the teaching status adjustment (if applicable), we multiply the teaching status adjustment (0.0784, in this example) by the wage-adjusted and rural-adjusted amount (if applicable). Finally, we add the additional teaching status payments (if applicable) to the wage, rural, and LIP-adjusted federal prospective payment rates. Table 6 illustrates the components of the adjusted payment calculation.

TABLE 6—EXAMPLE OF COMPUTING THE IRF FY 2015 FEDERAL PROSPECTIVE PAYMENT

Steps			Rural Facility A (Spencer Co., IN)		Urban Facility B (Harrison Co., IN)
1	Unadjusted Federal Prospective Payment		\$32,561.72		\$32,561.72
2	Labor Share	×	0.69294	×	0.69294
3	Labor Portion of Federal Payment	=	\$22,563.32	=	\$22,563.32
4	CBSA-Based Wage Index (shown in the Addendum, Tables 1 and 2)	×	0.8513	×	0.8852
5	Wage-Adjusted Amount	=	\$19,208.15	=	\$19,973.05
6	Non-Labor Amount	+	\$9,998.40	+	\$9,998.40
7	Wage-Adjusted Federal Payment	=	\$29,206.55	=	\$29,971.45
8	Rural Adjustment	×	1.149	×	1.000
9	Wage- and Rural-Adjusted Federal Payment	=	\$33,558.33	=	\$29,971.45
10	LIP Adjustment	×	1.0156	×	1.0454
11	FY 2015 Wage-, Rural- and LIP-Adjusted Federal Prospective Payment Rate	=	\$34,081.84	=	\$31,332.15
12	FY 2015 Wage- and Rural-Adjusted Federal Prospective Payment		\$33,558.33		\$29,971.45
13	Teaching Status Adjustment	×	0	×	0.0784
14	Teaching Status Adjustment Amount	=	\$0.00	=	\$2,349.76
15	FY 2015 Wage-, Rural-, and LIP-Adjusted Federal Prospective Payment Rate	+	\$34,081.84	+	\$31,332.15
16	Total FY 2015 Adjusted Federal Prospective Payment	=	\$34,081.84	=	\$33,691.92

Thus, the adjusted payment for Facility A would be \$34,081.84, and the adjusted payment for Facility B would be \$33,681.92.

VII. Update to Payments for High-Cost Outliers Under the IRF PPS

A. Update to the Outlier Threshold Amount for FY 2015

Section 1886(j)(4) of the Act provides the Secretary with the authority to make payments in addition to the basic IRF prospective payments for cases incurring extraordinarily high costs. A case qualifies for an outlier payment if the estimated cost of the case exceeds the adjusted outlier threshold. We calculate the adjusted outlier threshold by adding the IRF PPS payment for the case (that is, the CMG payment adjusted by all of the relevant facility-level adjustments) and the adjusted threshold amount (also adjusted by all of the relevant facility-level adjustments). Then, we calculate the estimated cost of a case by multiplying the IRF's overall CCR by the Medicare allowable covered charge. If the estimated cost of the case is higher than the adjusted outlier threshold, we make an outlier payment for the case equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold.

In the FY 2002 IRF PPS final rule (66 FR 41362 through 41363), we discussed our rationale for setting the outlier threshold amount for the IRF PPS so that estimated outlier payments would equal 3 percent of total estimated payments. For the 2002 IRF PPS final rule, we analyzed various outlier policies using 3, 4, and 5 percent of the total estimated payments, and we concluded that an outlier policy set at 3 percent of total estimated payments would optimize the extent to which we could reduce the financial risk to IRFs

of caring for high-cost patients, while still providing for adequate payments for all other (non-high cost outlier) cases.

Subsequently, we updated the IRF outlier threshold amount in the FYs 2006 through 2014 IRF PPS final rules and the FY 2011 and FY 2013 notices (70 FR 47880, 71 FR 48354, 72 FR 44284, 73 FR 46370, 74 FR 39762, 75 FR 42836, 76 FR 47836, 76 FR 59256, and 77 FR 44618, 78 FR 47860, respectively) to maintain estimated outlier payments at 3 percent of total estimated payments. We also stated in the FY 2009 final rule (73 FR 46370 at 46385) that we would continue to analyze the estimated outlier payments for subsequent years and adjust the outlier threshold amount as appropriate to maintain the 3 percent target.

To update the IRF outlier threshold amount for FY 2015, we proposed to use FY 2013 claims data and the same methodology that we used to set the initial outlier threshold amount in the FY 2002 IRF PPS final rule (66 FR 41316 and 41362 through 41363), which is also the same methodology that we used to update the outlier threshold amounts for FYs 2006 through 2014. Based on an analysis of this updated data, we estimate that IRF outlier payments as a percentage of total estimated payments are approximately 2.8 percent in FY 2014. Therefore, we update the outlier threshold amount to \$8,848 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2015.

We received 3 comments on the proposed update to the FY 2015 outlier threshold amount to maintain estimated outlier payments at approximately 3 percent of total estimated IRF payments, which are summarized below.

Comment: Several commenters expressed support for the proposed update to the outlier threshold amount to maintain estimated IRF outlier payments for FY 2015 at 3 percent of total IRF PPS payments. However, some commenters expressed concerns that actual IRF outlier payments in recent years have tended to fall below 3 percent of total IRF PPS payments. These commenters requested that we revise the methodology used to set the outlier threshold amount to ensure that we pay out the full 3 percent in outlier payments or incorporate any unused outlier payments from years in which aggregate outlier payments are below the 3 percent target back into the IRF PPS base payments for subsequent years.

Response: We will continue to monitor our IRF outlier policies to ensure that they continue to compensate IRFs for treating unusually high-cost patients and, thereby, promote access to care for patients who are likely to require unusually high-cost care. Although actual outlier payments in the most recent 4-year period have tended to be just slightly below the 3 percent target, actual outlier payments ranged at or above 3 percent for the 4-year period from FY 2007 through FY 2010. In fact, actual outlier payments in FY 2008 were 4.2 percent of total IRF PPS payments.

As we have indicated in previous IRF PPS final rules, we do not make adjustments to IRF PPS payment rates for the sole purpose of accounting for differences between projected and actual outlier payments. We use the best available data at the time to establish an outlier threshold for IRF PPS payments prior to the beginning of each fiscal year so that estimated outlier payments for that fiscal year will equal 3 percent of total estimated IRF PPS payments. We

evaluate the status of our outlier expenditures annually, and if there is a difference from our projection, that information is used to make a prospective adjustment to lower or raise the outlier threshold for the upcoming fiscal year. We believe a retrospective adjustment would not be appropriate. This includes instances where we have overestimated, as well as underestimated, outlier payments. If outlier payments for a given year turn out to be greater than projected, we do not recoup money from hospitals; if outlier payments for a given year are lower than projected, we do not make an adjustment to account for the difference. Payments for a given discharge in a given fiscal year are generally intended to reflect or address the average costs of that discharge in that year; that goal would be undermined if we adjusted IRF PPS payments to account for “underpayments” or “overpayments” in IRF outliers in previous years.

Final Decision: Having carefully considered the public comments received and also taking into account the most recent available data, we are finalizing the outlier threshold amount of \$8,848 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2015. This update is effective October 1, 2014. We will continue to monitor trends in IRF outlier payments to ensure that they are working as intended to compensate IRFs for treating exceptionally high-cost IRF patients.

B. Update to the IRF Cost-to-Charge Ratio Ceiling and Urban/Rural Averages

In accordance with the methodology stated in the FY 2004 IRF PPS final rule (68 FR 45674, 45692 through 45694), we apply a ceiling to IRFs' CCRs. Using the methodology described in that final rule, we update the national urban and rural CCRs for IRFs, as well as the national CCR ceiling for FY 2015, based on analysis of the most recent data that is available. We apply the national urban and rural CCRs in the following situations:

- New IRFs that have not yet submitted their first Medicare cost report.
- IRFs whose overall CCR is in excess of the national CCR ceiling for FY 2015, as discussed below.
- Other IRFs for which accurate data to calculate an overall CCR are not available.

Specifically, for FY 2015, we estimate a national average CCR of 0.569 for rural IRFs, which we calculated by taking an average of the CCRs for all rural IRFs using their most recently submitted cost

report data. Similarly, we estimate a national average CCR of 0.443 for urban IRFs, which we calculated by taking an average of the CCRs for all urban IRFs using their most recently submitted cost report data. We apply weights to both of these averages using the IRFs' estimated costs, meaning that the CCRs of IRFs with higher costs factor more heavily into the averages than the CCRs of IRFs with lower costs. For this final rule, we have used the most recent available cost report data (FY 2012). This includes all IRFs whose cost reporting periods begin on or after October 1, 2011, and before October 1, 2012. If, for any IRF, the FY 2012 cost report was missing or had an “as submitted” status, we used data from a previous fiscal year's (that is, FY 2004 through FY 2011) settled cost report for that IRF. We do not use cost report data from before FY 2004 for any IRF because changes in IRF utilization since FY 2004 resulting from the 60 percent rule and IRF medical review activities suggest that these older data do not adequately reflect the current cost of care.

In accordance with past practice, we will set the national CCR ceiling at 3 standard deviations above the mean CCR. Using this method, the national CCR ceiling would be 1.37 for FY 2015. This means that, if an individual IRF's CCR exceeds this proposed ceiling of 1.37 for FY 2015, we would replace the IRF's CCR with the appropriate national average CCR (either rural or urban, depending on the geographic location of the IRF). We calculated the national CCR ceiling by:

Step 1. Taking the national average CCR (weighted by each IRF's total costs, as discussed above) of all IRFs for which we have sufficient cost report data (both rural and urban IRFs combined).

Step 2. Estimating the standard deviation of the national average CCR computed in step 1.

Step 3. Multiplying the standard deviation of the national average CCR computed in step 2 by a factor of 3 to compute a statistically significant reliable ceiling.

Step 4. Adding the result from step 3 to the national average CCR of all IRFs for which we have sufficient cost report data, from step 1.

We did not receive any comments on the proposed updates to the IRF CCR ceilings and urban/rural averages.

Final Decision: As we did not receive any comments on the proposed updates to the IRF CCR ceiling and the urban/rural averages for FY 2015, we are finalizing the national average urban CCR at 0.443, the national average rural CCR at 0.569, and the national CCR ceiling at 1.37 percent for FY 2015.

These updates are effective October 1, 2014.

VIII. Refinements to the Presumptive Compliance Methodology

A. Background on the Compliance Percentage

The compliance percentage has been part of the criteria for defining IRFs since implementation of the Inpatient Prospective Payment System (IPPS) in 1983. In the September 1, 1983, interim final rule with comment period (48 FR 39752), which allowed IRFs to be paid separately from the IPPS, the initial compliance percentage was set at 75 percent. The 1983 interim rule stipulated that in accordance with sections 1886(d)(1)(B) and 1886(d)(1)(B)(ii) of the Act, a rehabilitation hospital and a rehabilitation unit were excluded from the IPPS. Sections 1886(d)(1)(B) and 1886(d)(1)(B)(ii) of the Act also give the Secretary the discretion to define a rehabilitation hospital and unit.

A hospital or unit deemed excluded from the IPPS and paid under the IRF PPS must meet the general requirements in subpart B and subpart P of part 412. Subject to the special payment provisions of § 412.22(c), a hospital or unit must meet the general criteria set forth in § 412.22 and in the regulations at § 412.23(b), § 412.25, and § 412.29 that specify the criteria for a provider to be classified as a rehabilitation hospital or unit. Hospitals and units meeting these criteria are eligible to be paid on a prospective payment basis as an IRF under the IRF PPS.

The 1983 interim final rule stipulated that one of the criteria for being classified as an IRF was that, during the facility's most recently completed 12-month cost reporting period, the hospital must be primarily engaged in furnishing intensive rehabilitation services, as demonstrated by patient medical records, indicating that at least 75 percent of the IRF's patient population were treated for one or more of the 10 medical conditions specified in the regulation that typically required the intensive inpatient rehabilitation treatment provided in an IRF. These criteria, along with other related criteria, distinguished an inpatient rehabilitation hospital or unit from a hospital that furnished general medical or surgical services, as well as rehabilitation services. We believed then, as we do now, that by examining the types of conditions for which a hospital's inpatients are treated, and the proportion of patients treated for conditions that typically require intensive inpatient rehabilitation, we

would be able to distinguish those hospitals in which the provision of rehabilitation services was primary rather than secondary. Thus, Medicare pays for rehabilitation services at IRFs at a higher rate than other hospitals because IRFs are designed to offer specialized inpatient rehabilitation care to patients with intensive needs.

The original medical conditions specified under the compliance percentage, or “75 percent rule,” were stroke, spinal cord injury, congenital deformity, amputation, major multiple trauma, fracture of femur (hip fracture), brain injury, and polyarthritis (including rheumatoid arthritis). In the January 3, 1984, final rule (49 FR 234), we expanded the list of eligible medical conditions to include neurological disorders (including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson’s disease) and burns. In the May 7, 2004 final rule (69 FR 25752), we modified and expanded the list of eligible medical conditions by removing polyarthritis and substituting three more clearly defined arthritis-related conditions. The three conditions that replaced polyarthritis included the following:

- Active, polyarticular rheumatoid arthritis, psoriatic arthritis, and seronegative arthropathies resulting in significant functional impairment of ambulation and other activities of daily living, which has not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission, or which results from a systemic disease activation immediately before admission, but has the potential to improve with more intensive rehabilitation.

- Systemic vasculitides with joint inflammation, resulting in significant functional impairment of ambulation and other activities of daily living, which has not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission, or which results from a systemic disease activation immediately before admission, but has the potential to improve with more intensive rehabilitation.

- Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease) involving three or more major joints (elbow, shoulders, hips, or knees) with joint deformity and substantial loss of range of motion, atrophy, significant

functional impairment of ambulation and other activities of daily living, which has not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission, but has the potential to improve with more intensive rehabilitation. (A joint replaced by a prosthesis is no longer considered to have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.)

In the May 7, 2004 final rule (69 FR 25752), a 13th condition was also added to include patients who undergo knee and/or hip joint replacement during an acute hospitalization immediately preceding the inpatient rehabilitation stay and also meet at least one of the following specific criteria:

- Underwent bilateral knee or hip joint replacement surgery during the acute hospitalization immediately preceding the IRF admission.
- Are extremely obese patients as measured by the patient’s Body Mass Index (BMI) of at least 50, at the time of admission to the IRF.
- Are patients considered to be “frail elderly,” as determined by a patient’s age of 85 or older, at the time of admission to the IRF (the provision currently states only that the patients be age 85 or older at the time of admission to the IRF).

In 2002, we surveyed Medicare fiscal intermediaries to determine how they were enforcing the 75 percent rule. Although the 75 percent rule was one of the criteria that were used to distinguish an IRF from an acute care hospital from 1983 to 2004, we found evidence that different fiscal intermediaries were enforcing the rule differently. We found fiscal intermediaries were using inconsistent methods to determine whether IRFs were in compliance with the regulation, and that some IRFs were not being reviewed for compliance at all. This led to concerns that some IRFs might have been out of compliance with the regulation and inappropriately classified as IRFs, while other IRFs may have been held to overly high standards. Because of these concerns we sought to establish a more uniform enforcement of the 75 percent rule.

In the May 16, 2003, IRF PPS proposed rule (68 FR 26786), we solicited comments on the regulatory requirements of the 75 percent rule. Though we did not, at that time, propose amending the regulatory requirements for the 75 percent rule located in then § 412.23(b)(2), we did propose to amend these requirements in

the September 9, 2003, proposed rule titled, “Medicare Program; Changes to the Criteria for Being Classified as an Inpatient Rehabilitation Facility” (68 FR 53266). In that rule, we proposed some revisions to the 75 percent rule, including lowering the compliance percentage to 65 percent during a 3-year transition period for cost reporting periods between January 1, 2004, and January 1, 2007. Also, in response to comments on the September 9, 2003, proposed rule and as stated above, the May 7, 2004, final rule (69 FR 25752) expanded the number of medical conditions that would meet the compliance percentage from 10 to 13 and provided that patient comorbidities may also be included in determining an IRF’s compliance with the requirements during the transition period.

In the September 9, 2003, proposed rule, we defined “comorbidity” as a specific patient condition that is secondary to the patient’s principal diagnosis or impairment that is the primary reason for the inpatient rehabilitation stay. In the May 7, 2004, rule, we adopted the provision to use a patient with a comorbidity counting towards the compliance threshold during the transition period. In the determination of the compliance percentage, a patient comorbidity counts toward the percentage if the comorbidity falls in one of the conditions specified at § 412.29(b)(2) and has caused significant decline in functional ability in the individual that even in the absence of the admitting condition, the individual would require the intensive rehabilitation treatment that is unique to IRFs.

Anticipating that IRFs needed some time to adjust and adapt their processes to the changes in the enforcement of the 75 percent rule, in the May 7, 2004 final rule, we provided IRFs with a 3-year phase-in period (cost reporting periods beginning on or after July 1, 2004, through July 1, 2007) to establish the compliance threshold of 75 percent of the IRF’s total patient population. The 3-year phase-in period was intended to begin with cost reporting periods on or after July 1, 2004, with the threshold at 50 percent of the IRF’s population and gradually increase to 60 percent, then to 65 percent, and then to expire with cost reporting periods beginning on or after July 1, 2007, when the compliance percentage would once again be at 75 percent.

Section 5005 of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted February 8, 2006) and section 1886(d)(1)(B) of the Act modified the provisions of the 75 percent rule originally specified in the May 7, 2004,

final rule. To reflect these statutory changes, in the August 7, 2007, final rule (72 FR 44284), we revised the regulations to prolong the overall duration of the phased transition to the full 75 percent threshold by stipulating that an IRF must meet the full 75 percent compliance threshold as of its first cost reporting period that starts on or after July 1, 2008. We also extended the policy of using a patient's comorbidities to the extent they met the conditions as outlined in the regulations to determine compliance with the classification criteria at then § 412.23(b)(2)(1) to the first cost reporting period that starts on or after July 1, 2008.

Subsequently, section 115 of the MMSEA amended section 5005 of the DRA to revise elements of the 75 percent rule that are used to classify IRFs. In accordance with the statute, in the August 8, 2008, final rule (73 FR 46370), we revised the compliance rate that IRFs must meet to be excluded from the IPPS and be paid under the IRF PPS to 60 percent for cost reporting periods beginning in or after July 1, 2006. Also, in accordance with the statute, we required that patient comorbidities that satisfy the criteria as specified at then § 412.23(b)(2)(i) [now located at § 412.29(b)(1) and § 412.29(b)(2)] be included in calculations used to determine whether an IRF meets the 60 percent compliance percentage for cost reporting periods beginning on or after July 1, 2007. As a result of these changes, the requirements started being referred to as the "60 percent rule," instead of the "75 percent rule." The regulations finalized in the FY 2009 IRF PPS final rule (73 FR 46370) continue to be in effect.

Though an IRF must serve an inpatient population of whom at least 60 percent meet the compliance percentage criteria specified at § 412.29(b), the existing regulation allows for 40 percent of reasonable and necessary admissions to an IRF to fall outside of the 13 qualifying medical conditions. Still, the 60 percent rule is one of the primary ways we distinguish an IRF from an acute care hospital. As Medicare payments for IRF services are generally significantly higher than Medicare payments for similar services provided in acute care hospital settings, we believe that it is important to maintain and enforce the criteria for medical conditions that may be counted toward an IRF's compliance calculation for the 60 percent rule to ensure that the higher Medicare payments are appropriately allocated to those providers that are providing IRF-level services.

B. Changes to the Diagnosis Codes That Are Used to Determine Presumptive Compliance

In the FY 2014 IRF PPS final rule (78 FR 47860, 47881 through 47895), we revised the list of ICD-9-CM diagnosis codes that are used to determine presumptive compliance, effective for compliance review periods beginning on or after October 1, 2014. These revisions were based on an analysis of the ICD-9-CM code list that determined the clinical appropriateness of each individual ICD-9-CM code's inclusion on the list. As a result of this analysis, we also intended to remove all of the status post-amputation diagnoses codes, but these codes were inadvertently omitted from the FY 2014 IRF PPS proposed and final rules. These codes, listed in Table 7, are used to indicate that a patient has the sequela or residual effect of a condition.

As we stated in the FY 2014 IRF PPS final rule (78 FR 47860, 47881), the ICD-9-CM diagnosis codes included on the "ICD-9-CM Codes That Meet Presumptive Compliance Criteria" list are ones that demonstrate that the patient meets criteria for the medical conditions that may be counted toward an IRF's compliance percentage under the presumptive compliance methodology. Further, we stated that the underlying premise of the presumptive compliance methodology list is that it represents particular diagnosis codes that, if applicable to a given patient, would more than likely mean that the patient required intensive rehabilitation services in an IRF for treatment of one or more of the conditions specified at § 412.29(b)(2) or that they had a comorbidity that caused significant decline in functional ability such that, even in the absence of the admitting condition, the patient would require the intensive rehabilitation treatment that is unique to IRFs and cannot be appropriately treated in another care setting. For the reasons described below, we do not believe that the ICD-9-CM diagnosis codes listed in Table 7 meet either of these criteria. We believe it is impossible to determine, from the presence of such diagnosis codes alone, whether a patient with an amputation status or prosthetic fitting and adjustment needs has a condition for which he or she would qualify for treatment in an IRF. Some patients with an amputation status or prosthetic fitting and adjustment needs will not require close medical supervision by a physician or weekly interdisciplinary team conferences to achieve their goals, while others may require these services. We believe that rehabilitation associated

with an amputation status or prosthetic fitting and adjustment needs does not necessarily need to be accompanied by the close medical management provided in IRFs, as long as the patient does not have any additional comorbidities that have caused significant decline in his or her functional ability that, in the absence of an amputation status or prosthetic fitting and adjustment needs, would necessitate treatment in an IRF. That is to say, a patient's need for intensive rehabilitation services provided in an IRF may depend on other conditions which cannot be solely identified through the presence of an amputation status or prosthetic fitting and adjustment diagnosis code. If a patient with one of the diagnosis codes listed in Table 7 has additional comorbidities that would necessitate treatment in an IRF, then those additional comorbidities would qualify the patient for inclusion in the calculation of the IRF's compliance percentage under the presumptive compliance methodology. Thus, we are removing the status post-amputation diagnosis codes listed in Table 7 from the list of "ICD-9-CM Codes That Meet Presumptive Compliance Criteria." The removal of these codes will be effective for compliance review periods beginning on or after October 1, 2015, and the changes will be incorporated into the ICD-10 lists (discussed below) when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions.

TABLE 7—ICD-9-CM CODES REMOVED FROM "ICD-9-CM CODES THAT MEET PRESUMPTIVE COMPLIANCE CRITERIA"

ICD-9-CM Code	Diagnosis
V49.65	Below elbow amputation status.
V49.66	Above elbow amputation status.
V49.67	Shoulder amputation status.
V49.73	Foot amputation status.
V49.74	Ankle amputation status.
V49.75	Below knee amputation status.
V49.76	Above knee amputation status.
V49.77	Hip amputation status.
V52.0	Fitting and adjustment of artificial arm (complete) (partial).
V52.1	Fitting and adjustment of artificial leg (complete) (partial).

We received 44 comments on the proposed changes to the diagnosis codes that are used to determine presumptive

compliance, which are summarized below.

Comment: Citing studies, several commenters emphasized that research indicates that amputees receive substantial benefits from care in the IRF setting compared to other post-acute care settings. Another commenter stated that proper fitting and training for the use of a prosthesis is a complex clinical exercise that requires the intensive multidisciplinary services provided in IRFs.

Response: We agree that some patients that present with an amputation status or prosthetic fitting or adjustment may require the close medical supervision by a rehabilitation physician and weekly interdisciplinary team conferences uniquely provided in IRFs to achieve their therapeutic goals. However, we believe that it cannot be determined from the amputation status or prosthetic fitting or adjustment diagnosis codes alone whether a patient presents with the clinical complexity that would require an IRF level of care. Indeed, we believe that many patients who are appropriately coded with these diagnosis codes can be effectively cared for in other care settings. As we stated in the FY 2015 IRF PPS proposed rule (79 FR 26308, 26327) and the FY 2014 IRF PPS final rule (78 FR 47860, 47881), the underlying premise of the presumptive compliance methodology list is that it represents particular diagnosis codes that, if applicable to a given patient, would more than likely mean that the patient required intensive rehabilitation services in an IRF for treatment of one or more of the conditions specified at § 412.29(b)(2) or that they had a comorbidity that caused significant decline in functional ability such that, even in the absence of the admitting condition, the patient would require the intensive rehabilitation treatment that is unique to IRFs and cannot be appropriately treated in another care setting. Therefore, we believe that the mere presence of an amputation status or prosthetic fitting or adjustment code alone does not provide us with enough information to determine whether the patient meets all of the requirements necessary to count for the 60 percent rule in § 412.29(b)(2).

Comment: One commenter suggested that the rationale provided by CMS for the removal of the amputation status codes confuses the concepts of medical necessity with IRF classification. The commenter stated that an amputee would only be admitted to a rehabilitation hospital by a rehabilitation physician if he or she needed intensive rehabilitation services. The commenter further stated that even

though many amputees may not need intensive inpatient rehabilitation services, the mere referral and subsequent admission to an IRF would mean that the patient needs the intensive services provided by the IRF.

Response: We disagree with this comment. The regulatory requirements at § 412.29(b) specify that at least 60 percent of an IRF's patient population must require intensive rehabilitation services in an IRF for treatment of one or more of the conditions specified at § 412.29(b)(2) or that they have a comorbidity that caused significant decline in functional ability such that, even in the absence of the admitting condition, the patient would require the intensive rehabilitation treatment that is unique to IRFs and cannot be appropriately treated in another care setting. For a patient to require intensive rehabilitation services in an IRF for treatment of a particular condition, that patient must require the close medical supervision and interdisciplinary approach to care that are unique to care in an IRF. This is not based on the IRF coverage requirements, but rather it is based directly on the regulatory language in § 412.29(b) that details the requirements that IRFs must meet to adhere to the 60 percent rule and thereby be classified for payment under the IRF PPS.

Comment: Several commenters stated that the proposed removal of the status post amputation diagnoses codes from "ICD-9-CM Codes That Meet Presumptive Compliance Criteria" list would limit access to patients that would meet admission criteria as specified in § 412.29(b)(2). One commenter stated that the effect of the proposed removal of the amputation status post diagnosis codes would be to cause more IRFs to have to undergo medical review, and the IRFs would respond by restricting admission for certain types of patients in order to avoid having to go through medical review.

Response: We do not believe that the proposed removal of these diagnosis codes will have a significant effect on access to care for these patients, as we estimate that only about 2 percent of all IRF patients are currently coded with these diagnoses, and these diagnosis codes are only used to meet the 60 percent rule requirements 0.3 percent of the time. In addition, the proposed removal of these codes from the presumptive compliance method does not necessarily mean that a patient with one of these diagnosis codes cannot be included in the IRF's population that meets the 60 percent rule. As we described in the FY 2014 IRF PPS final

rule, we use a bifurcated sub-regulatory approach to determining compliance with the rule, in which an IRF's data is first evaluated to determine whether or not the IRF is presumptively compliant with the 60 percent rule requirements. If so, then the IRF is presumed to meet the regulatory requirements. If not, then the IRF is evaluated using the more intensive medical review compliance method. If a patient with one of these diagnosis codes presents with the clinical complexity that would require an IRF level of care, then this information can be determined by the medical review, and the patient can then be included in the IRF's patient population that meets the 60 percent rule requirements. We will closely monitor the data to ensure that there are no unintended consequences of these policies on access to care.

Comment: One commenter stated that amputations in older adult populations are often the byproduct of multiple comorbid conditions (for example, diabetes or peripheral vascular disease) that make this population more at risk for post-surgical complications, such as risk of non-healing surgical incision.

Response: We agree that a patient with multiple comorbid conditions, such as diabetes or peripheral vascular disease affecting the surgical stump incision, may present with a need for intensive rehabilitation services provided in an IRF that could not be solely identified through the presence of an amputation status or prosthetic fitting or adjustment diagnosis code. These patients may meet the 60 percent rule requirements based on the presence of one of their other comorbid conditions, or the patients' clinical complexity may be determined on medical review, and the patient can then be included in the IRF's patient population that meets the 60 percent rule requirements.

Comment: One commenter requested that we apply any changes to the presumptive compliance methodology to an IRF's full 12-month compliance review period, instead of applying them to only part of an IRF's compliance review period.

Response: As the commenter suggested, all of the proposed changes to the presumptive compliance methodology are being applied effective for full 12-month compliance review periods, and will not be applied to only part of an IRF's compliance review period.

Comment: Several commenters suggested that we delay implementation of the proposed removal of the amputation status diagnosis codes and the other changes to the presumptive

compliance methodology. For example, one commenter specifically recommended that we delay implementation of changes to the presumptive compliance methodology until changes to the IRF-PAI and the associated limited medical review process are implemented. Another commenter recommended that we delay implementation of any further changes to the presumptive compliance method until at least October 1, 2015, and one commenter recommended that we delay implementation of any changes to the “non-specific ICD codes,” which we finalized in the FY 2014 IRF PPS final rule (78 FR 47884 through 47887), for at least one year following the implementation of the ICD-10-CM medical code data set, to give providers more time to adapt to the added specificity of the coding provided for under ICD-10-CM. Another commenter suggested that we delay implementation of the changes to the presumptive compliance method to give us more time to thoroughly evaluate the policies, since the changes to the presumptive compliance method that we finalized in the FY 2014 IRF PPS final rule and the changes to the presumptive compliance method that we proposed in the FY 2015 IRF PPS proposed rule, taken together, would cause as many as 15 percent of IRF Medicare cases to fail the presumptive compliance method. Finally, several commenters recommended that we keep the ICD-9-CM codes used in the presumptive compliance method as they are now—as of the date of this final rule, neither the changes finalized in the FY 2014 IRF PPS nor the changes proposed in the FY 2015 IRF PPS proposed rule have taken effect—or delay implementation of additional IGC exclusions until we transition to ICD-10-CM.

Response: We agree with these commenters that delaying the effective date of the changes to the presumptive compliance method would give CMS more time to put processes in place to mitigate some of the additional burden of increased medical reviews, and would allow providers more time to adapt to these changes. Though several of the commenters explicitly recommended that we delay the changes to the presumptive compliance method that were proposed in the FY 2015 IRF PPS proposed rule, none of the commenters explicitly stated that we should delay implementation of the changes to the presumptive compliance method that we finalized in the FY 2014 IRF PPS final rule. However, we interpret several of the comments to mean that we should delay both sets of

changes, so as to effectuate all of the related policies at the same time. For example, several of the commenters suggested delaying implementation of the “presumptive compliance” changes, without distinguishing between the changes that we finalized in the FY 2014 IRF PPS final rule and the changes that we proposed in the FY 2015 IRF PPS proposed rule. In addition, one commenter referred specifically to the impetus for recommending a delay being the significant impact that the changes would have on “15 percent” of IRF cases that would no longer meet the presumptive compliance criteria. Other commenters referenced this “15 percent” figure as the percentage of IRF cases that would be affected if we were to change from using the current presumptive compliance method to using the revised presumptive compliance method that would result from both the changes that we finalized in the FY 2014 IRF PPS final rule and the changes that were proposed in the FY 2015 IRF PPS proposed rule. Thus, we believe that the commenter was recommending a delay of both sets of presumptive compliance method changes, so as to effectuate all of the related policies at the same time.

Therefore, based on our review of these comments, and to allow for the revisions to the IRF-PAI and the associated limited medical review process discussed in section X. of this final rule to take effect prior to implementation of the changes to the presumptive compliance method, we are implementing all of the changes to the presumptive compliance method for compliance review periods beginning on or after October 1, 2015. That is, we are delaying the effective date of the changes to the presumptive compliance method that we finalized in the FY 2014 IRF PPS final rule until compliance review periods beginning on or after October 1, 2015, and we are also delaying the changes to the presumptive compliance method that we are finalizing in this final rule so that they also take effect for compliance review periods beginning on or after October 1, 2015. This represents a one-year delayed effective date for all of these changes. We believe that it will be much less confusing for providers to have all of the changes to the presumptive compliance method take effect at the same time.

We do not believe that it is necessary to delay implementation of these changes for an additional year after ICD-10-CM becomes the required medical code data set for use on IRF claims and on the IRF-PAI. Given that the effective date of the use of ICD-10-

CM has been delayed twice, and given that the ICD-10-CM code lists, which will be used when ICD-10-CM becomes the required medical code data set with respect to IRF claims and the IRF-PAI, are available for download on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html> in conjunction with the publication of this final rule, we believe that IRFs will have sufficient opportunity to become familiar with the added specificity of the coding offered in ICD-10-CM.

Comment: Several commenters suggested that CMS continue to count amputation status codes toward an IRF’s compliance percentage, but do so in conjunction with other related information provided in the IRF-PAI. The commenters stated that the amputation status codes could be used in combination with the Etiologic Diagnosis, which would reflect recent injury. One commenter suggested that an indicator could be added that could be “paired up” with the codes in order to maintain automation and avoid the burden of increased medical review. Another commenter stated that comorbid conditions listed on the IRF-PAI could also provide an appropriate clinical picture that would “presumptively” indicate that the patient meets conditions outlined at § 412.29(b)(2). Moreover, one commenter suggested that the added specificity of coding provided for in the ICD-10-CM coding may supply additional information that may help support the amputation status diagnosis as a “presumptively” qualifying condition.

Response: We thank the commenters for their suggestions. However, we continue to believe that it cannot be determined from the amputation status or prosthetic fitting or adjustment diagnosis codes alone whether a patient presents with the clinical complexity that would require an IRF level of care, and, for this reason, we do not believe that it is appropriate to continue to include these codes on the “ICD-9-CM Codes That Meet Presumptive Compliance” list. However, as we indicated above, these patients can continue to be counted under the medical review methodology if their clinical complexity is shown in the medical record to require an IRF level of care. In fact, as the one commenter mentioned, the patient’s comorbid conditions as listed on the IRF-PAI and described in the patient’s medical record do contribute to an overall “picture” of the patient’s condition, but at this time, this information cannot be

determined using a computer program and can only be determined through a medical review of the patient's clinical record.

While we agree that ICD-10-CM coding will likely provide more specificity and more information, we continue to believe that these amputation status or prosthetic fitting or adjustment diagnosis codes, even under ICD-10-CM, do not provide enough information about the clinical complexity of the case to warrant continued inclusion on the list of diagnosis codes that meets the presumptive compliance criteria. We will consider the commenters' suggestions for future refinements to the IRF-PAI and to the presumptive compliance methodology.

Comment: One commenter recommended that CMS ensure that MACs understand the importance of IRF care to patients with amputations (especially those with other comorbidities) since there could be an increase in medical review for amputation cases.

Response: We appreciate the commenter's suggestion, and we plan to carry out training and outreach with MACs to review policy changes to the presumptive compliance methodology.

Final Decision: After carefully considering the comments that we received on the proposed removal of the status post-amputation diagnoses codes from the "ICD-9-CM Codes That Meet Presumptive Compliance Criteria" list, we are finalizing these proposed changes to the list. The changes to the list of diagnosis codes that are used to determine presumptive compliance under the 60 percent rule are effective for compliance review periods beginning on or after October 1, 2015.

C. Changes to the Impairment Group Codes That Meet Presumptive Compliance Criteria

An "impairment group code" is not an ICD diagnosis code, but part of a separate unique set of codes specifically developed for the IRF PPS for assigning the primary reason for admission to an IRF. These codes are listed in the IRF-PAI Training Manual (see section II, item #21, and Appendix A). The IRF-PAI Training Manual is available through the Internet on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html>.

If an IRF is eligible to use the presumptive methodology to evaluate its compliance with the 60 percent rule, all of its IRF-PAI assessments from the most recently completed 12-month compliance review period are examined

(with the use of a computer program) to determine whether they contain any of the codes listed on the presumptive methodology lists (that is, "ICD-9-CM Codes That Meet Presumptive Compliance Criteria" and "Impairment Groups That Meet Presumptive Compliance Criteria"). Each selected assessment is presumptively categorized as either meeting or not meeting the IRF 60 percent rule requirements based upon the primary reason for the patient to be treated in the IRF (the impairment group) and the ICD diagnosis codes listed as either the etiologic diagnosis (the etiologic problem that led to the condition for which the patient is receiving rehabilitation) or one of 25 comorbidities on the assessment.

Not all impairment group codes (IGCs) meet the presumptive compliance criteria. The underlying premise of the list of eligible IGCs that are used to determine presumptive compliance (similar to the diagnosis codes listed in "ICD-9-CM Codes That Meet Presumptive Compliance Criteria") includes particular IGCs that, if applicable to a given patient, would more than likely mean that the patient required intensive rehabilitation services for treatment of one or more of the conditions specified at § 412.29(b)(2). The current list of eligible IGCs that meet presumptive compliance criteria, Appendix B: Impairment Group Codes That Meet Presumptive Compliance Criteria, can be downloaded from the October 1, 2007, IRF Compliance Rule Specification Files on the Medicare IRF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Criteria.html>. Again, this list contains only those IGCs that meet the presumptive compliance criteria.

1. Removal of IGCs for Unilateral Upper Extremity Amputations and Arthritis From Appendix B: Impairment Group Codes That Meet Presumptive Compliance Criteria

In the FY 2014 IRF PPS final rule (78 FR 47889 through 47895), we finalized (applicable for compliance review periods beginning on or after October 1, 2014) the removal of certain ICD-9-CM codes for unilateral upper extremity amputations from the list of "ICD-9-CM Codes That Meet Presumptive Compliance Criteria" because we believed that it is impossible to determine, from the presence of such ICD-9-CM codes alone, whether a patient with such a unilateral upper extremity amputation has a condition for which he or she would need intensive rehabilitation services for

treatment of one or more of the conditions specified in § 412.29(b)(2). Further, we stated that a patient's need for intensive inpatient rehabilitative services for the treatment of one or more of these conditions would depend on the presence of additional comorbidities that caused significant decline in his or her functional ability to an extent that would necessitate treatment in an IRF. If the patient has one or more of the comorbidities on the list of "ICD-9-CM Codes That Meet Presumptive Compliance Criteria," then the patient would already qualify as meeting the presumptive compliance criteria. We concluded that if the diagnosis codes for such a patient's comorbidities do not appear on the list of "ICD-9-CM Codes That Meet Presumptive Compliance Criteria," then the patient could still be considered for inclusion in the IRF's compliance percentage following medical review and confirmation that the case meets the criteria for one or more of the medical conditions in the regulations.

In the FY 2014 IRF PPS final rule (78 FR 47887 through 47895), we also finalized (applicable for compliance review periods beginning on or after October 1, 2014) the removal of ICD-9-CM diagnosis codes for arthritis conditions from the list of "ICD-9-CM Codes That Meet Presumptive Compliance Criteria" because the inclusion of patients with these medical conditions in the presumptive compliance calculation of the IRF's compliance percentage is conditioned on those patients meeting the described severity and prior treatment requirements. However, the ICD-9-CM diagnosis codes that reflect these arthritis and arthropathy conditions do not provide any information about the severity of the condition or whether the prior treatment requirements were met. Therefore, we stated in the FY 2014 IRF PPS final rule that we believe that additional information beyond the presence of the code is necessary to determine if the medical record would support inclusion of individuals with the arthritis and arthropathy conditions outlined in our regulations under § 412.29(b)(2)(x) through § 412.29(b)(2)(xii) in the presumptive compliance calculation of the facility's compliance percentage. For this reason, we finalized the removal of the ICD-9-CM diagnosis codes associated with the medical conditions outlined in our regulations under § 412.29(b)(2)(x) through § 412.29(b)(2)(xii) from the list of "ICD-9-CM Codes That Meet Presumptive Compliance Criteria." However, we also stated that we expect

that the MACs will be able, upon medical review, to include those patients in a facility's compliance percentage upon confirmation that the severity and prior treatment requirements were met.

Consistent with our rationale in the FY 2014 IRF PPS final rule for removing the ICD-9-CM diagnoses codes for unilateral upper extremity amputations and the arthritis and arthropathy conditions, we are making conforming changes to the IGCs in this final rule by removing four IGCs from Appendix B: Impairment Group Codes That Meet Presumptive Compliance Criteria. Thus, we will remove the following codes from Appendix B: Impairment Group Codes That Meet Presumptive Compliance Criteria:

- IGC 0005.1—Unilateral Upper Limb Above the Elbow (AE),
- IGC 0005.2—Unilateral Upper Limb Below the Elbow (BE),
- IGC 0006.1—Rheumatoid Arthritis, and
- IGC 0006.9—Other Arthritis.

2. Other Changes to Appendix B: Impairment Group Codes That Meet Presumptive Compliance Criteria

We will revise Appendix B: Impairment Group Codes That Meet Presumptive Compliance Criteria by revising the diagnosis codes listed as exclusions on the table and by revising the title of the table.

In the FY 2014 IRF PPS final rule (78 FR 47860, 47881 through 47895), we finalized (applicable for compliance review periods beginning on or after October 1, 2014) the removal of certain ICD-9-CM codes from the list of "ICD-9-CM Codes That Meet Presumptive Compliance Criteria." Accordingly, we exclude these diagnosis codes from counting if they are the patient's Etiologic Diagnosis (that is, the etiologic problem that led to the condition for which the patient is receiving rehabilitation). That is, a given IGC that would otherwise meet the presumptive compliance criteria will not meet such criteria if the patient has one of the "excluded" Etiologic Diagnoses for that IGC.

In addition, in the FY 2014 IRF PPS final rule (78 FR 47860, 47883), we implemented a change in the titles of some tables used in the presumptive compliance methodology to no longer use alphabet characters or the "Appendix" labels to identify these tables. Consistent with the intent to reduce confusion among tables, and effective October 1, 2014, we will identify Appendix B: Impairment Group Codes That Meet Presumptive Compliance Criteria as "Impairment

Group Codes That Meet Presumptive Compliance Criteria."

In addition, we provided an additional new table, "Impairment Group Codes That Meet Presumptive Compliance Criteria," that lists Etiologic Diagnosis codes that are excluded from counting under related IGCs in ICD-10-CM code format. For example, ICD-10-CM code G72.3, "Periodic Paralysis" is an excluded Etiologic Diagnosis code under IGC 0003.8, "Neuromuscular Disorders." Further, to accommodate the Etiologic Diagnosis code exclusions, we have reformatted this table. A revised table containing the "Impairment Group Codes That Meet Presumptive Compliance Criteria," with the ICD-10-CM Etiologic Diagnosis exclusions, can be viewed on the Medicare IRF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html>. The changes to the table, "Impairment Group Codes That Meet Presumptive Compliance Criteria," will be effective for compliance review periods beginning on or after October 1, 2015.

We received 49 comments on the proposed changes to the impairment group codes that meet presumptive compliance criteria, which are summarized below.

Comment: Several commenters expressed concerns that a potential unintended consequence of excluding the proposed arthritis diagnosis codes under IGCs 0008.51, 0008.52, 0008.61, 0008.62, 0008.71, and 0008.72 would be that most lower extremity joint replacement cases that currently satisfy the 60 percent rule, that is, bilateral joint replacement cases and unilateral joint replacement cases involving patients 85 years of age or older and/or who have a BMI of 50 or greater, would no longer be included in an IRF's presumptive compliance percentage.

Response: We appreciate the commenters' careful review of the proposed Etiologic Diagnosis exclusions for IGCs 0008.51, 0008.52, 0008.61, 0008.62, 0008.71, and 0008.72, and we agree with these commenters that there would have been unintended consequences of excluding the proposed arthritis diagnosis codes from these IGCs. As we intend to continue to count bilateral lower-extremity joint replacement cases and unilateral lower-extremity joint replacement cases involving patients 85 years of age or older and/or who have a BMI of 50 or greater as meeting the 60 percent rule criteria under the presumptive compliance method, we will remove the proposed Etiologic Diagnosis exclusions

from IGCs 0008.51, 0008.52, 0008.61, 0008.62, 0008.71, and 0008.72.

Comment: Several commenters expressed concern that the impact of the proposed changes to the presumptive compliance criteria, the changes proposed in the FY 2015 proposed rule and the changes finalized in the FY 2014, will be to increase the number of IRFs that will fail to meet presumptive compliance.

Response: We agree with commenters that one of the likely consequences of the changes to the presumptive compliance method will be an increase in the number of IRFs that will fail the presumptive compliance method and will have to be evaluated using the medical review method. However, we believe that the proposed changes to the IGCs That Meet Presumptive Compliance Criteria are necessary to continue appropriate enforcement of the regulations in § 412.29(b). We believe that it is impossible to determine from the presence of one of the IGCs or Etiologic Diagnoses alone whether the patient's clinical complexity requires an IRF level of care, or, in the case of an arthritis code, whether the patient meets the severity and prior treatment requirements in regulation at § 412.29(b)(2). This information can only be obtained through a review of the patient's medical record.

However, to mitigate some of the added burden on providers of the additional medical reviews, we discuss a new policy in section X of this final rule that will allow some arthritis cases to count toward the presumptive compliance method based on a limited medical review of these cases. We believe that this new policy will alleviate some of the burden associated with additional medical reviews.

Comment: One commenter expressed concern about the removal of IGC 0005.1—Unilateral upper limb above the elbow (AE) and IGC 0005.2—Unilateral upper limb below the elbow (BE), as the commenter said that these patients have impairments related to the ability to conduct activities of daily living that are most appropriately treated using the intensive rehabilitation therapy provided in an IRF.

Response: As we indicated in the FY 2014 IRF PPS final rule (78 FR 47860, at 47890), we believe that some patients with upper extremity amputations might require treatment in an IRF, depending on the clinical complexity of the particular case or the presence of any other complicating factors or comorbidities. However, we expect that many patients with these upper extremity amputations will not require close medical supervision by a

physician or weekly interdisciplinary team conferences to achieve their goals, and can be treated effectively in other care settings. If the patient has additional comorbidities causing significant decline in his or her functional ability which, in the absence of the unilateral upper extremity amputation, would require treatment in an IRF, then the patient will still be able to be counted towards meeting the 60 percent rule criteria. Additionally, the patient can still be counted towards meeting the 60 percent rule criteria on medical review, if appropriate.

However, we continue to believe that a patient's need for the intensive rehabilitation services provided in an IRF depends on other factors which cannot be adequately determined through the mere presence of IGC 0005.1—Unilateral upper limb above the elbow (AE) and IGC 0005.2—Unilateral upper limb below the elbow (BE). Thus, we are removing these IGCs from the IGCs That Meet the Presumptive Compliance Criteria.

Comment: One commenter expressed concern about the proposed addition of non-specific diagnosis codes to the Etiologic Diagnosis exclusions for some of the IGCs because this commenter said that it is often “administratively unrealistic” to obtain detailed medical information from a transferring facility, especially in cases where the IRF admission is not directly from an acute care hospital. The commenter said that non-specific codes should not be viewed as reflecting poor documentation or poor coding.

Response: As we stated in the FY 2014 IRF PPS final rule (78 FR 47860, 47884), we believe that highly descriptive coding provides the best and clearest way to document the appropriateness of a given patient's admission, and would improve our ability to use the presumptive compliance method of calculating a facility's 60 percent rule compliance percentage. Therefore, whenever possible, we believe that the most specific code that describes a medical disease, condition, or injury should be used to document diagnoses on the IRF-PAI. We also stated in the FY 2014 IRF PPS final rule (78 FR 47860, 47884) that we believe imprecise codes would inappropriately categorize an overly broad segment of the patient population as having the conditions required for inclusion in a facility's presumptive compliance calculation, which would result in an inflated compliance percentage. In the FY 2014 IRF PPS final rule (78 FR 47860, 47885), we also stated that if the IRF does not have enough information about the patient's

condition to code the more specific codes on the IRF-PAI, we would expect the IRF to seek out additional information from the patient's acute care hospital medical record to determine the appropriate, more specific code to use. The ICD-9-CM diagnosis codes that are listed as exclusions on “Impairment Group Codes That Meet Presumptive Compliance Criteria” are consistent with the list of diagnosis codes we removed from “ICD-9-CM Codes That Meet Presumptive Compliance Criteria.”

Comment: Several commenters expressed concerns about possible inconsistencies in the specific IGC exclusions that we proposed in the FY 2015 IRF PPS proposed rule. For example, one commenter pointed out that we were proposing to exclude the Etiologic Diagnosis of ICD-9-CM code 850.5—Concussion with loss of consciousness of unspecified duration for IGC 0002.22—Brain dysfunction, Traumatic, Closed Injury. However, we were not proposing to exclude, ICD-9-CM code 850.0—Concussion with no loss of consciousness from this same IGC.

Response: We thank the commenter for their careful review and analysis of the IGCs That Meet Presumptive Compliance Criteria. We have reviewed the IGCs That Meet Presumptive Compliance Criteria in light of these comments, and we agree with the commenter's suggestion that this represents an inadvertent inconsistency. Thus, we are adding ICD-9-CM code 850.0—Concussion with no loss of consciousness as an Etiologic Diagnosis exclusion to the list of Etiologic Diagnosis exclusions under IGC 0002.22—Brain dysfunction, Traumatic, Closed Injury.

Comment: One commenter stated that we excluded ICD-9-CM diagnosis code 438.20—Late effects of cerebrovascular disease, hemiplegia affecting unspecified side from IGC 0001.9—Other Stroke, but did not list this diagnosis code as an exclusion for other stroke IGCs.

Response: ICD-9-CM diagnosis code 438.20 is not listed as an exclusion for the other stroke IGCs because the other stroke IGCs either specify side of body involvement or no paresis.

Comment: One commenter suggested that as many as 10 percent of IRF cases will no longer qualify toward an IRF's presumptive compliance percentage should the proposed removal of IGC 0005.1, IGC 0005.2, IGC 0006.1, and IGC 0006.9 and the exclusion of Rheumatoid and Osteoarthritis diagnosis codes from hip and knee joint replacement be finalized.

Response: As discussed above, the commenters led us to discover that there would have been unintended consequences of excluding the proposed arthritis Etiologic Diagnosis codes from IGCs 0008.51, 0008.52, 0008.61, 0008.62, 0008.71, and 0008.72. As we intend to continue to count bilateral lower-extremity joint replacement cases and unilateral lower-extremity joint replacement cases involving patients 85 years of age or older and/or who have a BMI of 50 or greater as meeting the 60 percent rule criteria under the presumptive compliance method, we are removing the proposed Etiologic Diagnosis exclusions from these IGCs. We believe that this change substantially reduces the estimated percentage of IRF cases that will no longer qualify toward an IRF's presumptive compliance percentage. However, with respect to the remaining IRF cases that will no longer qualify toward an IRF's presumptive compliance percentage, we continue to believe that this is appropriate because the case's compliance with the 60 percent rule criteria cannot be adequately determined through the mere presence of the IGC or ICD-9-CM diagnosis code alone.

Comment: Several commenters indicated that the proposed changes to “Impairment Group Codes That Meet Presumptive Compliance Criteria” (and the above discussed removal of the amputation status diagnosis codes) would likely lead to reduced access to IRF care. The commenters noted that for certain types of patients, IRFs would be in the position of choosing between admitting these patients and facing “additional risk” associated with medical reviews, or not admitting these types of patients. Many of these commenters said that such changes are unnecessary in light of past regulatory actions, such as the regulatory refinements of the 60 percent rule that were implemented in 2004 and the more stringent IRF coverage requirements that were implemented in 2010, that have already reduced the number of IRF admissions and increased the average IRF case mix.

Response: We acknowledge that some IRFs may seek to avoid the possibility of medical review by limiting admission of patients with certain conditions, such as arthritis or unilateral upper-extremity amputations. However, this is not our intent in implementing this policy. The intent of these changes to the presumptive compliance method is to obtain enough information to ensure that patients who are counted as meeting the 60 percent rule in § 412.29(b) are appropriately meeting

the regulatory requirements. Although previous regulatory refinements have improved the IRF payment system, we believe that the proposed updates to the presumptive compliance method serve to further enhance the accuracy and appropriateness of the payment system. As discussed in section X. of this final rule, we are concurrently implementing policies designed to minimize the burden created by the operational aspects of this policy.

Comment: One commenter suggested that the removal of IGC 0006.1—Rheumatoid Arthritis and IGC 0006.9—Other Arthritis should coincide with the implementation of the proposed new IRF–PAI item, so that these IGCs could still be used to presumptively determine an IRF’s compliance with the 60 percent rule. The commenter also suggested that the new IRF–PAI item and associated limited medical review should replace the current policy of requiring a full medical review if an IRF fails the presumptive compliance method.

Response: We agree with the commenter’s suggestion that the effective date of the removal of IGC 0006.1—Rheumatoid Arthritis and IGC 0006.9—Other Arthritis should coincide with the implementation of the new proposed IRF–PAI item. Additionally, we believe that it makes the most sense to implement the changes to the presumptive methodology, both those that were finalized in the FY 2014 IRF PPS final rule and those that we are finalizing in this section of this final rule, for compliance review periods beginning on or after October 1, 2015, to aid in mitigating the potential burden for additional medical review as a result of the finalized policy changes. As discussed in more detail in section X. of this final rule, the new IRF–PAI item for arthritis conditions will allow IRFs to indicate whether there are any arthritis codes (either IGC or ICD–9–CM diagnosis codes) on a patient’s IRF–PAI that meet all of the regulatory requirements specified in § 412.29(b)(2)(x), (xi), or (xii). If so, then we will perform a limited medical review on these cases to ensure that the requirements are met. If we find that all of the requirements are met, those arthritis cases will be allowed to count toward the IRF’s presumptive compliance percentage. As the new IRF–PAI item is being added for IRF discharges occurring on or after October 1, 2015, we believe it makes sense to delay the effective dates of the changes to the presumptive methodology finalized in the FY 2014 IRF PPS final rule and those changes to the presumptive methodology being finalized in this section of this final

rule. Therefore, we are delaying the effective date of the presumptive methodology changes finalized in the FY 2014 IRF PPS final rule and the additional presumptive methodology changes that we are finalizing in this section of this final rule, so that they will become effective for compliance review periods beginning on or after October 1, 2015.

However, we do not agree with the suggestion that the limited medical review should replace the full medical review entirely. The medical review method has been the more detailed and comprehensive method for enforcing the 60 percent rule since the rule was first implemented in the mid-1980s, and continues to be an important way of accurately determining whether IRFs meet the criteria in § 412.29(b) to be excluded from the IPPS and be paid instead under the IRF PPS.

Comment: One commenter expressed concern that the changes to the presumptive compliance methodology finalized in the FY 2014 IRF PPS final rule and the changes proposed in the FY 2015 IRF PPS proposed rule constitute an “end run” around the statutory limit on the compliance threshold of 60 percent established by Congress.

Response: We disagree with the commenter’s assertion that we are changing the 60 percent compliance threshold. We do not believe that the changes finalized in the FY 2014 IRF PPS final rule or the changes proposed in the FY 2015 IRF PPS proposed rule erode the underlying principle of the 60 percent rule that requires an IRF to demonstrate that it “served an inpatient population of whom at least 60 percent required intensive rehabilitation services for treatment of one or more of the conditions specified at paragraph (b)(2).” We are not revising the criteria that govern the 13 medical conditions that may be counted toward an IRF’s 60 percent rule compliance percentage. As we have stated in the FY 2014 IRF PPS final rule and the FY 2015 IRF PPS proposed rule, we are refining the lists used for the presumptive compliance methodology because we believe that certain ICD diagnosis codes on the lists do not necessarily demonstrate a patient’s meeting the medical condition (including severity and prior treatment) requirements for inclusion in a facility’s 60 percent compliance calculation under the presumptive methodology method. Thus, we are removing these codes so that the presumptive methodology lists better reflect the regulations. Furthermore, the criteria under which a case may count under medical review have not changed.

Comment: Several commenters stated that ICD–9–CM codes 820.8—Closed fracture of unspecified part of neck of femur and 820.9—Open fracture of unspecified part of neck of femur should not be exclusions under IGC 0008.11—Status Post Unilateral Hip Fracture and IGC 0008.12—Status Post Bilateral Hip Fractures. The commenters said that the ICD–9–CM codes 820.8 and 820.9 are often used as Etiologic Diagnoses in combination with IGCs 0008.11 and 0008.12. One commenter said that the diagnosis codes 820.8 and 820.9 still represent a hip fracture and that the more specific information regarding where on the neck of the femur the fracture occurred would not be readily available to the IRF and would in any case not meaningfully impact care.

Response: The use of an ICD–9–CM code beginning with 820, by definition, indicates that the patient has experienced a fracture of the neck of the femur. However, this code requires that decimal points be used following the number to ensure specificity. Diagnosis codes 820.00 through 820.32, by differentiating between an intracapsular and an extracapsular fracture of the proximal femur, provide a degree of specificity not offered by diagnosis codes 820.8 and 820.9. Therefore, as we proposed, we will exclude ICD–9–CM codes 820.8 and 820.9 as Etiologic Diagnosis codes under IGC 0008.11—Status Post Unilateral Hip Fracture and IGC 0008.12—Status Post Bilateral Hip Fractures. IGC 0008.11 and IGC 0008.12 will continue to count toward 60 percent compliance under the presumptive compliance method if coded with Etiologic Diagnosis codes 820.00 through 820.32.

Final Decision: After carefully considering the comments that we received on the proposed changes to the IGCs That Meet Presumptive Compliance Criteria, we are revising the list of excluded ICD–9–CM diagnosis codes for some IGCs from “Impairment Group Codes That Meet Presumptive Compliance Criteria” as follows: We are removing the ICD–9–CM diagnosis code exclusions under IGC 0008.51 through IGC 0008.72. We are also excluding ICD–9–CM diagnosis code 850.0 under IGC 0002.22. The final “Impairment Group Codes That Meet Presumptive Compliance Criteria” list that reflects specific changes to the proposed policies listed above, is available for download from the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html>. The presumptive methodology changes that we had finalized in the FY 2014 IRF

PPS final rule and the additional presumptive methodology changes that we are finalizing in this section of this final rule will become effective for compliance review periods beginning on or after October 1, 2015.

IX. Data Collection of the Amount and Mode (Individual, Concurrent, Group, and Co-Treatment) of Therapy Provided in IRFs According to Occupational, Speech, and Physical Therapy Disciplines

Prior to the implementation of the IRF PPS in January 2002, Medicare payment for IRF services under section 101(a) of the Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97–248, enacted September 3, 1982) was based on the reasonable costs incurred in furnishing services to Medicare beneficiaries, subject to a limit on allowable costs per discharge. Thus, for therapy services, Medicare reimbursed IRFs based on the reasonable costs incurred in furnishing appropriate levels of Individual Therapy or Group Therapy, which meant that IRFs had limited financial incentives to provide more of one mode of therapy than another. We presumed that decisions about the mode of therapy delivery were likely to be based on the needs of the patient and on the best way to assist patients in meeting their individualized rehabilitation goals. With the advent of the IRF PPS beginning in January 2002, Medicare began reimbursing IRFs using a set prospective payment amount that was intended to cover the costs of all treatment and services, including therapy services, provided to patients in the IRF. This increased the financial incentives for IRFs to give patients more Group Therapy and less Individual Therapy, because Individual Therapy is more costly to provide. Although we know that the financial incentives for the provision of Individual Therapy and Group Therapy changed, we do not know whether IRFs provided different modes of therapy in response to the new incentives or how much Individual Therapy and Group Therapy IRFs currently provide. Medicare does not currently collect data from IRFs on the amount of Individual, Concurrent, Group, and Co-Treatment Therapies provided by therapy discipline. We believe that it is important to begin collecting these data to determine what services Medicare is paying for under the IRF prospective payment system, which would allow us to analyze whether we are paying appropriately for services currently rendered by IRFs. Medicare administrative data (such as the IRF claims data) do not currently provide the level of detailed information

about the mode and type of therapy provided to IRF patients that we need to perform these analyses. Thus, this proposed new data collection will assist us in the development of appropriate coverage and payment criteria for the provision of Group Therapy in the IRF setting. We believe that these coverage and payment criteria are important to balance the beneficial aspects of Group Therapy for certain patients in certain instances with the IRF requirements for an intensive rehabilitation therapy program.

In the FY 2010 IRF PPS proposed rule (74 FR 21070, 21071), in which we proposed a revised set of Medicare coverage requirements for IRF services, we discussed the relative value of Individual Therapy versus Group Therapy in the IRF setting. To improve our understanding of when Group Therapy is most appropriate in IRFs, we solicited comments in that proposed rule on the types of patients for whom Group Therapy is appropriate, and the specific amount of Group Therapy that may be beneficial for these types of patients. Subsequently, we discussed the comments in the FY 2010 IRF PPS final rule (74 FR 39796, 39797).

Although the comments on the FY 2010 IRF PPS proposed rule did not offer any clinical study results or any data that would be helpful to us in developing coverage and payment criteria for the provision of Group Therapy in IRFs, the comments did suggest an important role for Group Therapy in the provision of therapies in IRFs. However, the majority of commenters remarked that Group Therapy should be limited in some way. Many commenters agreed that Group Therapy is a good adjunct to Individual Therapy, but should not be the primary source of therapy services provided in IRFs. Several commenters recommended that we limit the amount of Group Therapies provided in IRFs, and that we also limit the number of patients who can participate in a Group Therapy session. Commenters also suggested that Group Therapy sessions should be comprised of patients with similar diagnoses. We agreed with the commenters that Group Therapy should not be the primary source of therapy given to patients in IRFs. Group Therapy should be used in IRFs primarily as an adjunct to Individual Therapy services, which is the standard of care in IRFs, as Group Therapy may not uniformly represent the level of intensive rehabilitation therapy required and paid for in the IRF setting. In the final rule, we also stated that we would consider adopting specific coverage and payment criteria for Group Therapy

practice in IRFs through future rulemaking.

When an authorized clinician deems it to be necessary, we continue to believe that Group Therapy can serve as an appropriate mode of therapy delivery that can be beneficial to the particular needs of IRF patients as an adjunct to Individual Therapy. Anecdotally, we understand that Group Therapy remains a widely used mode of therapy in the IRF setting. But as we stated in the FY 2010 IRF PPS final rule, we believe that it would be inappropriate for IRFs to provide essentially all therapy in the form of Group Therapy because we do not believe that this is in the best interest of the patients, or that it reflects the services for which the IRF prospective payment system was established to pay. Therefore, to better understand the ways in which therapy services are currently being provided in IRFs, we are adding a new Therapy Information Section to the IRF-PAI to record the amount and mode of therapy (that is, Individual, Concurrent, Group, and Co-Treatment) patients receive in each therapy discipline (that is, physical therapy, occupational therapy, and speech-language pathology).

For purposes of recording therapy services in IRFs, we proposed to define Individual Therapy as the provision of therapy services by one licensed or certified therapist (or licensed therapy assistant, under the appropriate direction of a licensed or certified therapist) to one patient at a time (this is sometimes referred to as “one-on-one” therapy). In the proposed rule, we defined Group Therapy as the provision of therapy services by one licensed or certified therapist (or licensed therapy assistant, under the appropriate direction of a licensed or certified therapist) to between 2 and 6 IRF patients at one time, regardless of whether those 2 to 6 IRF patients are performing the same activity or different activities. As discussed in our responses to comments below, we will instead define Group Therapy as one licensed or certified therapist (or licensed therapy assistant, under the appropriate direction of a licensed therapist) treating 2 to 6 patients at the same time who are performing the same or similar activities. We proposed to define Co-Treatment as the provision of therapy services by more than one licensed or certified therapist (or licensed therapy assistant, under the appropriate direction of a licensed therapist) from different therapy disciplines to one patient at the same time. For example, Co-Treatment could involve one physical therapist and one occupational therapist working with one patient at

the same time to achieve the patient's goals. Because Co-Treatment is appropriate for specific clinical circumstances and is not suitable for all patients, its use should be limited. As discussed in our responses to comments below, we will define Concurrent Therapy as one licensed or certified therapist treating 2 patients at the same time who are performing different activities.

We will collect this information in a new Therapy Information Section on the IRF-PAI, which will be effective for IRF discharges beginning on or after October 1, 2015. The new Therapy Information section will be completed as part of the patient's discharge assessment. In this new section, the IRF will record how many minutes of Individual, Concurrent, Group, and Co-Treatment Therapies the patient received, according to each therapy discipline (that is, physical therapy, occupational therapy, and speech-language pathology), during the first week (7 calendar day period) of the IRF stay; how many minutes of Individual, Concurrent, Group, and Co-Treatment Therapies the patient received, according to each therapy discipline, during the second week (7 calendar day period) of the IRF stay. In the proposed rule, we proposed that IRFs would also collect the average number of minutes of Individual, Group, and Co-Treatment therapies the patient received, according to each therapy discipline, during all subsequent weeks (7 calendar day periods) of the IRF stay, beginning with the third week. For Co-Treatment, each therapist will record the amount of time spent with the patient. That is, if a physical therapist and an occupational therapist both worked with the patient from 9:00 a.m. to 9:30 a.m., then each therapist would record 30 minutes with the patient in the Co-Treatment section of the IRF-PAI. The draft of the IRF-PAI for FY 2016 that includes this new Therapy Information section is available for download from the IRF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAL.html> in conjunction with the publication of this final rule. We will use these data for the following purposes:

- To analyze the types of therapy services Medicare is currently paying for under the IRF prospective payment system; and
- To monitor the amount of therapy given and the use of different therapy modes in IRFs to support future rulemaking in this area.

For example, we are considering using these data to propose limits on the amount of Group Therapy that may be

provided in IRFs through future rulemaking. One such limit that we are currently considering is that an IRF patient may receive no more than 25 percent of his or her total therapy treatment time in Group Therapy, similar to the limit that currently exists in the skilled nursing facility (SNF) setting, as discussed in the FY 2000 SNF PPS and Consolidated Billing final rule (64 FR 41644, 41662). We specifically solicited public comment on all of these proposals, including whether 25 percent is the most appropriate limit to establish for the IRF setting.

We received 43 comments on the data collection regarding the amount and mode (Individual, Concurrent, Group, and Co-Treatment) of therapy provided in IRFs according to Occupational, Speech, and Physical Therapy Disciplines, which are summarized below.

Comment: Overall, several commenters supported CMS's proposed therapy collection item on the IRF-PAI, with one commenter indicating that collection of these data could lead to significant improvements in quality of care and accuracy of payments in the IRF PPS.

Response: We appreciate the support from the commenters regarding the new therapy item on the IRF-PAI. To date, we have been unable to track changes in the provision of therapy to patients because Medicare does not collect data on therapy modalities (Individual, Concurrent, Group, and Co-Treatment) by each therapy discipline (that is, physical therapy, occupational therapy, and speech-language pathology). We believe that by adding this item to the IRF-PAI, we will be able to determine the current services for which Medicare is paying and whether limits on the amount of group therapy that may be provided to IRF patients are needed.

Comment: Several commenters expressed concern that the proposed collection method changes the collection criteria for the weeks subsequent to the second week. Commenters suggested that this change introduces the potential for confusion and error because facilities will have to monitor every patient on the unit to determine when the third week of the stay will begin. Additionally, these commenters suggested that we should collect data on the total number of minutes of therapy provided to patients, by mode and type of therapy, only once at discharge based on the total number of minutes provided to the patient throughout the IRF stay, as it would lessen the burden of the data collection.

Response: After careful consideration of these comments, we agree that

collecting average number of minutes of therapy, by mode and type of therapy, for weeks 3 and beyond may have the potential to create confusion for providers. For this reason and in order to minimize provider burden, we are choosing not to finalize this proposal, and will instead only collect total number of minutes of therapy by mode and discipline for weeks 1 and 2. We believe that it would greatly improve our understanding of the provision of therapy in IRFs to collect data on the amount of therapy provided, by mode and type of therapy, for week 1 of the IRF stay (that is, the first 7 consecutive calendar days starting with the day of admission) and for week 2 of the IRF stay (that is, the second 7 consecutive calendar days of the IRF stay). Since the average length of stay in an IRF is 13 days, and to minimize the burden of this data collection effort, we will not require data to be reported beyond week 2 of the IRF stay. We believe that collecting total number of minutes of therapy, by mode and type of therapy, only for weeks 1 and 2 of the IRF stay is sufficient to help us to be able to develop future policy and improve the quality of care and accuracy of payments in the IRF PPS. Additionally, since our intent is to collect the most specific information regarding therapy data that we can, we recognize that collecting the average amount of therapy for weeks 3 and on, will perhaps not provide us with the specificity that we are seeking at this time. However, we may propose to require data collection on weeks 3 and beyond of the IRF stay through future notice and comment rulemaking if we later determine that such data is needed to better inform future policymaking.

While we recognize that the commenters believe that collecting the number of minutes of therapy, by mode and type of therapy, for the whole IRF stay only at the time of the patient's discharge from the IRF would lessen the burden of this data collection, we do not believe that this would provide us with level of detail that we believe we would need to develop future policy in this area or to understand what services we are paying for with the IRF benefit.

Comment: Several commenters suggested that CMS should seek to achieve its objective of better understanding therapy usage and outcomes within IRFs, by funding a study on the utilization of various therapy modes in IRFs.

Response: Unfortunately, we are not able to fund a study of therapy usage and outcomes, but we would welcome learning from such studies conducted by others. Clinical evidence linking

therapy usage with patient outcomes would greatly improve our understanding of these issues, and would not only enhance future policymaking in this area, but we believe would also inform and enhance the quality of care provided in IRFs and other post-acute care settings.

Comment: Several commenters expressed concern regarding CMS's definition of each therapy mode, most specifically, Group Therapy. One commenter suggested that we should be more consistent in our definitions of the different modes of therapy across Medicare payment settings. Many of the commenters indicated that studies regarding the benefits of one mode of therapy over another are very limited, and wanted to know what clinical basis we used when deciding that a group should be comprised of 2–6 patients. Other commenters urged CMS to recognize Concurrent Therapy as a distinct mode of therapy and not include it in the Group Therapy definition.

Response: After carefully reviewing the comments regarding the definitions of the different modes of therapy, we agree with commenters that Concurrent Therapy should be removed from the definition of Group Therapy and recognized as a distinct mode of therapy. We initially included Concurrent Therapy with Group Therapy because we wanted to lessen the burden on providers. However, we understand from the comments that separating out Concurrent Therapy from Group Therapy may actually make it easier for providers to report the data, as they already record data separately according to Concurrent Therapy and Group Therapy in the medical record. We also understand from the comments that it would make it easier for providers if we were to use the same definitions for the different modes of therapy, to the extent feasible, across Medicare's post-acute care settings. We believe that such consistency across settings will serve to improve the accuracy and reliability of the data we receive. As we also believe that it would be useful for us to better understand the provision of Concurrent Therapy in IRFs, separate from the provision of Group Therapy, we are revising our proposal, and will collect data instead on Individual, Concurrent, Group, and Co-Treatment Therapies.

Furthermore, in response to comments, we will generally define these terms using the same definitions for Individual, Concurrent, and Co-Treatment, that we currently use in the SNF PPS (see Chapter 3 Sec. O of the Minimum Data Set (MDS) Manual,

version 3.0 located at, <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html>). We generally concur that, when appropriate, it is important to apply definitions consistently across Medicare's post-acute care settings. Thus, we are defining Individual Therapy as the provision of therapy services by one licensed or certified therapist (or licensed therapy assistant, under the appropriate direction of a licensed or certified therapist) to one patient at a time (this is sometimes referred to as "one-on-one" therapy), Co-Treatment as the provision of therapy services by more than one licensed or certified therapist (or licensed therapy assistant, under the appropriate direction of a licensed therapist) from different therapy disciplines to 1 patient at the same time, and Concurrent Therapy as one licensed or certified therapist treating 2 patients at the same time who are performing different activities. However, we have decided not to use the exact SNF definition for Group Therapy in IRFs. Based on our review of the public comments, we believe it is appropriate to broaden the SNF definition for the purposes of this IRF data collection effort. We may still consider changes to the definition of Group Therapy for the IRF setting in the future, based on our review of the data we receive and based on any additional feedback from providers. In the SNF setting, the data collection regarding Group Therapy is used to allocate a therapist's time for the purpose of classifying a particular patient into the appropriate case-mix group for payment. Since the purpose of the data collection in the IRF setting differs, we believe that the same interpretation is not needed. Additionally, since we have decided to separate Concurrent Therapy from the definition of Group Therapy, we have changed the definition of Group Therapy to ensure patients are performing the same or similar activities. Two patients performing different activities would now be defined as Concurrent Therapy. We will define Group Therapy as the provision of therapy services by one licensed or certified therapist (or licensed therapy assistant, under the appropriate direction of a licensed or certified therapist) treating 2 to 6 patients at the same time who are performing the same or similar activities.

We plan to update the IRF-PAI Training Manual to inform providers, in more detail, regarding completion of the Therapy Data Collection Section.

We agree with many of the commenters that evidence regarding the clinical efficacy of the various modes of therapy for different patient populations is lacking. In the FY 2010 IRF PPS proposed rule (74 FR 21052, 21070), we specifically asked for this type of information, and the commenters told us that such information is largely unavailable. We would welcome any information that might be available to better understand this issue. However, we believe that the absence of such clinical evidence makes it all the more imperative that we start by collecting data on the amounts, types, and modes of therapy provided in IRFs to inform future policymaking.

We do not specifically know of the existence of any clinical evidence on the optimal number of patients for Group Therapy. We would be interested in any studies that developed such clinical evidence. In the absence of such evidence and solely for the purposes of collecting the data, we proposed to define Group Therapy as one therapist working with 2 to 6 patients at the same time. We proposed 6 patients as the upper limit for group therapy in IRFs because we believe that more than 6 patients in a group would likely make the group more difficult for a therapist to supervise and manage, and might decrease the benefits to patients of the group interaction. We did not receive any comments suggesting that a Group Therapy session in an IRF should include more than 6 patients, and in fact received several comments in support of using 6 as an upper limit on the number of patients. Thus, we will use the definition of Group Therapy as one therapist working with 2 to 6 patients who are all performing the same or similar activities solely for the purposes of this data collection effort. We may consider revising this definition for the IRF setting through future rulemaking based on the availability of new evidence or further feedback on this issue.

Comment: While a few commenters were supportive of our consideration of 25 percent as the most appropriate limit to establish for the provision of Group Therapy in the IRF setting, the majority of commenters urged CMS not to by impose a 25 percent threshold limiting the amount of Group Therapy an IRF patient can receive. Many commenters said that a potential cap on the provision of Group Therapy in IRFs was premature in the absence of data and studies to support an appropriate limit. These commenters also indicated that such a limit would not sufficiently recognize the professional judgment of the treating clinicians who, they believe,

are best equipped to determine the modality and duration of therapy a patient needs. Additionally, several commenters suggested that IRF patients should not be held to the same therapy standards and assignment of minutes as SNF patients since the two populations are very different.

Response: While we appreciate the positive feedback from the commenters who supported the idea of a potential threshold, after careful review of the comments, the majority of commenters suggested placing a cap on the amount of Group Therapy that IRF patients should receive would be premature at this time. We appreciate the concerns raised by these commenters and believe that it would be prudent to give more consideration to setting a cap, and the appropriate threshold for such a cap, regarding the provision of Group Therapy. We believe that collecting and analyzing the current delivery of therapy services will help inform any future policymaking. At such time that we believe a threshold is needed on the amount of Group Therapy provided, we will consider policy development through notice and comment rulemaking.

If, through future rulemaking, we do decide to impose a Group Therapy threshold, we do not believe that this would limit the professional judgment of the treating clinicians. We know that clinicians are best equipped to determine the modality and duration of therapy that any particular patient needs. With that being said, we believe that the preponderance of therapy given in an IRF should be Individual, since that is the only way that we believe that an IRF patient is truly receiving the intensive rehabilitation therapy program typically provided in an IRF, and we want to be sure that continues to be the standard. A potential threshold for the provision of group therapy in IRFs would serve to further clarify what we mean by “preponderance.”

Comment: One commenter expressed concern that we might believe that all IRF patients should receive 100 percent individual therapy. Another commenter suggested that we explicitly recognize the clinical value that Group Therapy provides over other therapy modes for certain patients.

Response: We do not believe that all IRF patients should only receive individualized therapy. We understand that different types of patients need different motivation and various forms of therapy in order to achieve their therapy goals. As we indicated in the proposed rule (79 FR 26329), when an authorized clinician deems it to be necessary, we continue to believe that

Group Therapy can serve as an appropriate mode of therapy delivery that can be beneficial to the particular needs of IRF patients as an adjunct to Individual Therapy. An important goal of rehabilitation is community reintegration and groups are important to that process. The interaction with other patients provides tremendous psychosocial benefits, providing encouragement and confidence in skills learned. However, we believe that the preponderance of therapy provided to patients in IRFs should be individual therapy in order to reflect the intensity of therapy provided in IRFs.

Comment: Several commenters suggested that we provide additional information about how IRFs should allocate or attribute minutes among patients participating in a Concurrent Therapy or Group Therapy session on the IRF-PAI.

Response: We will include more detailed information regarding completion of the Therapy Data Collection Section of the IRF-PAI in an update to the IRF-PAI Training Manual that we will post on the IRF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS> prior to October 1, 2015.

Final Decision: After careful consideration of the comments we received on the proposed therapy data collection on the IRF-PAI, we are finalizing our collection of data on the amount and mode (that is, Individual, Concurrent, Group, and Co-Treatment) of therapy provided in the IRF setting according to therapy discipline (that is, physical therapy, occupational therapy, and speech-language pathology). These data will be collected on a revised IRF-PAI form which is available for download from the CMS Web site [<http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/index.html>] in conjunction with this final rule. This requirement will become effective for IRF discharges occurring on or after October 1, 2015.

X. Revision to the IRF-PAI for Arthritis Conditions

In the FY 2014 IRF PPS final rule (78 FR 47860, 47881 through 47895), we revised the list of ICD-9-CM diagnosis codes used to determine presumptive compliance, effective for compliance review periods beginning on or after October 1, 2014. As part of these revisions, we removed all of the ICD-9-CM codes for arthritis conditions because we found that such codes did not provide any information as to whether the patients met the severity and prior treatment requirement

portions of the criteria for the medical conditions that may be counted toward an IRF's compliance percentage under the presumptive compliance method. As we said in the FY 2014 IRF PPS final rule, we did not adopt any and all arthritis conditions in the May 7, 2004, final rule (69 FR 25752). Rather, we only included certain kinds of arthritic conditions which met defined severity and prior treatment requirements. We anticipated that less severe arthritic conditions could be satisfactorily managed outside of IRFs, as these cases would not require the intensive therapy provided in the inpatient rehabilitation setting.

We received a number of comments on the FY 2014 IRF PPS proposed rule (78 FR 26880) regarding the proposed removal of the ICD-9-CM codes for arthritis. The majority of commenters suggested that removing ICD-9-CM codes for arthritis would increase the use of the medical review method, which is more burdensome for both CMS and for IRFs. Several commenters suggested that IRFs should not be required to undergo a “full medical review” if they fail to meet the required compliance percentage using the presumptive compliance method. Instead, commenters suggested use of a “limited medical review” in which only arthritis and systemic vasculidities cases would be reviewed. We said in the FY 2014 IRF PPS final rule (78 FR 47860 at 47888 through 47889) that we would use the time afforded by the 1-year delayed implementation to consider the feasibility of minimizing any burdens created by the operational aspects of this policy.

In keeping with what we stated in the FY 2014 IRF PPS final rule, in the FY 2015 IRF PPS proposed rule (79 FR 26308 at 26330 through 26331), we proposed to add an item to the IRF-PAI form for an IRF to record the specific arthritis diagnosis code(s) for each patient that meets the severity and prior treatment requirements outlined in the regulation. By coding arthritis diagnosis codes in this section, the IRF would indicate that the patient's arthritis conditions met all of the severity and prior treatment requirements (as outlined in regulation at § 412.29(b)(2)(x) through § 412.29(b)(2)(xii)) to be counted toward an IRF's compliance percentage under the presumptive compliance method.

The purpose of the proposed new item is to provide us with the additional severity and prior treatment information necessary for us to identify the arthritis diagnoses that are appropriate to count toward an IRF's compliance percentage under the presumptive compliance

method, thus reducing the medical review burden. If an IRF's presumptive compliance percentage is below the compliance threshold (currently, 60 percent), but inclusion of the arthritis codes reported in the new proposed data item would result in the IRF's presumptive compliance percentage meeting or exceeding the compliance threshold, then we proposed to perform a "limited" medical review on a statistically valid random sample of the cases documented under this new proposed item to ensure that the severity and prior treatment requirements were actually met. The number of cases from the statistically valid random sample found to meet the severity and prior treatment requirements would be extrapolated to the total number of cases documented under the new proposed item (that is, if 70 percent of the cases in the statistically valid random sample meet the severity and prior treatment requirements, we would presume that 70 percent of all of the cases documented in the new proposed item met the severity and prior treatment requirements). If the IRF's presumptive compliance percentage meets or exceeds the compliance threshold (currently, 60 percent) with the addition of the compliant cases documented under the new proposed item, then the IRF will be presumed to meet the 60 percent rule requirements using the presumptive compliance method. However, if the number of compliant cases documented under the new proposed item does not result in the IRF's presumptive compliance percentage meeting or exceeding the compliance threshold (currently 60 percent), then the normal medical review procedures for IRFs not meeting the compliance threshold (currently 60 percent) under the presumptive compliance method would apply. A draft of the proposed new IRF-PAI for FY 2016, with the new proposed item, was made available for download on the IRF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html> in conjunction with the release of the proposed rule.

The purpose of the proposal is to reduce the medical review burden associated with the removal of the ICD-9-CM codes for arthritis conditions from the presumptive methodology, while still allowing us to ensure that the arthritis diagnosis codes included in the calculation of an IRF's compliance percentage under the presumptive compliance method meet the severity

and prior treatment regulatory requirements.

We received 21 comments on our proposed revision to the IRF-PAI to add a data item for arthritis conditions, which are summarized below.

Comment: Several commenters supported the proposed revision to the IRF-PAI to allow providers to indicate whether the case coded with the arthritis condition met the prior treatment and severity requirements. Commenters especially supported the associated limited medical review process as described in the proposed rule. However, many commenters said that asking IRFs to code the arthritis diagnosis codes twice would create confusion, increase provider burden, and possibly lead to duplicative coding. Several commenters suggested that we instead provide for a simplified yes/no field on the IRF-PAI to indicate whether the case meets the prior treatment and severity regulatory requirements.

Response: We appreciate the commenters' suggestions. Based on our review of the suggestions offered by the commenters, we believe that a much simpler approach than what we had proposed would be to provide an item on the IRF-PAI allowing the IRF to indicate whether or not the IRF-PAI contains any arthritis codes which meet the severity and prior treatment regulatory requirements at § 412.29(b)(2)(x) through § 412.29(b)(2)(xii). This approach would also be easier to administer. Thus, we are adopting this change to item #24A of the IRF-PAI form, instead of the additional IRF-PAI item that had been proposed for that item. The new item #24A would instead ask the IRF to mark the box if there are any arthritis codes listed in items #21, 22, or 24 that meet the severity and prior treatment regulatory requirements at § 412.29(b)(2)(x) through § 412.29(b)(2)(xii).

Comment: Several commenters indicated that IRFs are sometimes unable to obtain the necessary information about a patient's course of treatment prior to the IRF admission. These commenters suggested that the prior treatment requirements should be removed from the regulation.

Response: The requirement that patients with arthritis conditions admitted to IRFs must not have shown adequate improvement following an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings has been in regulation since this requirement was finalized in the May 7, 2004 final rule (69 FR 25752). As stated in that final

rule, the rehabilitation prescriptions for many types of arthritis conditions, especially osteoarthritis, typically involve outpatient therapy several times a week for 4 weeks or more. Although we recognized in that final rule that some very unusual cases may require intensive therapies and the interdisciplinary approach to care typically provided in IRFs, we believe that patients should have participated in a required course of appropriate, sustained, and aggressive outpatient treatment (or treatment in a less-intensive setting) which failed to improve the patient's condition in order to demonstrate that the IRF admission is reasonable and necessary. This requirement allows us to be able to count toward the 60 percent rule those "exceptional" cases that the IRF is able to demonstrate truly require the intensive and interdisciplinary level of care provided in an IRF, without counting the majority of cases we believe do not represent the type of patient requiring intensive rehabilitation in an IRF.

These requirements have been in regulation for almost a decade. Until now, IRFs have not expressed any concerns to us regarding their inability to obtain the required prior treatment information, and many IRFs treat a significant number of these patients. We do not believe difficulties obtaining prior treatment information are a widespread problem among IRFs. Further, we believe that a patient's prior course of treatment is useful and important clinical information for the treating physicians and therapists in the IRF to design the most effective treatment plan for the patient. Thus, we believe that the prior treatment information is necessary and important information for the IRF to obtain, both to meet the regulatory requirements and to provide the most effective care to the patient, and we disagree with the commenter's suggestion that this requirement should be removed from the regulation.

Final Decision: After carefully considering the comments we received on the proposed new item on the IRF-PAI to indicate the arthritis codes that meet the prior treatment and severity regulatory requirements, we are modifying our proposal, based on the commenters' suggestions, to simplify it. Instead of the new item we had proposed for item #24A on the IRF-PAI, we will instead ask IRFs to mark the box in item #24A if there are any arthritis codes listed in items #21, 22, or 24 that meet the severity and prior treatment regulatory requirements at § 412.29(b)(2)(x) through

§ 412.29(b)(2)(xii). If an IRF's presumptive compliance percentage is below the compliance threshold (currently, 60 percent), but inclusion of the cases that have been marked in the affirmative in the new item #24A in the IRF's presumptive compliance percentage would cause the IRF's presumptive compliance percentage to exceed 60 percent, then we will perform a "limited" medical review on a statistically valid random sample of such cases. The number of cases from the statistically valid random sample that are found to meet the severity and prior treatment requirements would be extrapolated to the total number of cases that have been marked in the affirmative by the IRF in the new item #24A. For example, if 70 percent of the IRF's cases in the statistically valid random sample are found to meet the severity and prior treatment requirements, we would presume that 70 percent of all of the IRF's cases marked in the affirmative by the IRF in the new item #24A met the severity and prior treatment requirements. If the IRF's presumptive compliance percentage meets or exceeds the compliance threshold (currently, 60 percent) with the addition of the compliant cases that are found to meet the severity and prior treatment requirements by this method, then the IRF will be presumed to meet the 60 percent rule requirements using the presumptive compliance method. However, if the number of compliant cases that are found to meet the severity and prior treatment requirements by this method do not result in the IRF's presumptive compliance percentage meeting or exceeding the compliance threshold (currently 60 percent), medical review procedures for IRFs not meeting the compliance threshold (currently 60 percent) under the presumptive compliance method would apply. A draft of the proposed new IRF-PAI for FY 2016, with the simpler item #24A, is available for download on the IRF PPS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAL.html> in conjunction with this final rule.

Because item #24A is specifically intended to mitigate some of the burden of additional medical reviews that would be required as a result of the refinements to the presumptive compliance method that are finalized in section VIII of this final rule, we believe that this change to the IRF-PAI should have an effective date that is as close as possible to the effective date of the refinements to the presumptive compliance method. However, as noted

in section VIII of this final rule, the refinements to the presumptive compliance method are effective for compliance review periods beginning on or after October 1, 2015, but changes to the IRF-PAI must instead be implemented for all IRF discharges occurring on or after a specific date and cannot be done on a compliance review period basis. Thus, an effective date for new IRF-PAI item #24A of October 1, 2015, will enable this change to take effect on or before any IRFs are subject to the new presumptive compliance method. This change to the IRF-PAI is effective for IRF discharges on or after October 1, 2015.

XI. International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), Conversion

A. Background on the Use of Diagnosis Information in the IRF PPS

As described in section I.C. of this final rule, IRFs are required to complete the appropriate sections of a PAI, designated as the IRF-PAI, upon the admission and discharge of a Medicare Part A Fee-for-Service patient. In addition, beginning with IRF discharges occurring on or after October 1, 2009, the IRF is also required to complete the appropriate sections of the IRF-PAI upon the admission and discharge of each Medicare Part C (Medicare Advantage) patient, as described in the FY 2010 IRF PPS final rule (74 FR 39762, 39798 through 39800). Several sections of the IRF-PAI (currently, items #22, 24, 46, and 47) require IRFs to report diagnosis information for patients. Until ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions, we will continue to use the ICD-9-CM medical data code set. Medicare uses the diagnosis information recorded on the IRF-PAI for the following purposes:

(1) To case-mix adjust the IRF PPS payment for a patient by assigning the patient to an appropriate payment tier based on the patient's comorbidities.

(2) To determine, using the presumptive compliance method, whether an IRF presumptively meets the 60 percent rule requirements in § 412.29(b).

As described in more detail in the FY 2002 IRF PPS final rule (66 FR 41316), we developed a list of diagnosis codes (previously, ICD-9-CM codes) that, if coded as a comorbidity in item #22 on a patient's IRF-PAI, would result in that patient being assigned to one of three higher-paying payment tiers under the IRF PPS. In the FY 2006 IRF PPS final rule (70 FR 57166), we updated and

revised the list of diagnosis codes (at that time, ICD-9-CM codes). We refer to the current list of diagnosis codes that, if present on a patient's IRF-PAI, result in the patient being assigned to a higher-paying tier as the "List of Comorbidities" in this final rule.

In addition to determining the appropriate tier assignment for case-mix adjusting IRF PPS payments, the diagnosis coding on the IRF-PAI is also used within the presumptive compliance method that typically serves as the first step in determining an IRF's compliance with the 60 percent rule. As discussed in more detail in section VII. of this final rule, the presumptive compliance method is one of two ways that MACs may evaluate an IRF's compliance with the 60 percent rule (the other method being the medical review method). The diagnosis coding on the IRF-PAI assessments from an IRF's most recently completed 12-month compliance review period are examined (with the use of a computer program) to determine whether they contain any of the diagnosis codes that are listed in the "ICD-9-CM Codes That Meet Presumptive Compliance Criteria" (which is also known as the presumptive methodology list).

Additionally, the computer program examines the impairment group codes, which are not ICD-9-CM or ICD-10-CM codes, but are instead part of a separate unique set of codes specifically developed for the IRF PPS for assigning the primary reason for admission to an IRF. The computer program compares the impairment group codes listed in item #21 to the list of "Impairment Group Codes That Meet Presumptive Compliance Criteria" to determine whether the patient's impairment group code presumptively meets the 60 percent rule requirements. In certain cases, the list of "Impairment Group Codes That Meet Presumptive Compliance Criteria" contains Etiologic Diagnosis exclusions. For example, impairment group code 0005.4, which represents a unilateral lower limb amputation below the knee is included on the list of "Impairment Group Codes that Meet Presumptive Compliance Criteria," unless the associated Etiologic Diagnosis recorded on the patient's IRF-PAI in item #22 is 895.0 (under ICD-9-CM), which indicates a traumatic amputation of the toe or toes. Therefore, the list of "Impairment Group Codes That Meet Presumptive Compliance Criteria" contains diagnosis code information (currently ICD-9-CM codes) in addition to impairment group codes.

These lists contain diagnosis code information (currently in the form of

ICD-9-CM diagnosis codes) which is used to case-mix adjust payments, determine an IRF's presumptive compliance with the 60 percent rule, and to assist IRFs in accurately completing the impairment group code information on the IRF-PAI. As such, these lists must all be converted to ICD-10-CM for the IRF PPS to assign payments and classify IRF facilities appropriately when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions.

B. Conversion of Diagnosis Information From ICD-9-CM to ICD-10-CM for the IRF PPS

In the September 5, 2012, final rule, "Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier; Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for the International Classification of Diseases, 10th Edition (ICD-10-CM and ICD-10-PCS) Medical Data Code Sets" (77 FR 54664), the Department of Health and Human Services announced a delay in the implementation of the ICD-10-CM and ICD-10-PCS code sets from October 1, 2013, to October 1, 2014. The transition to the ICD-10 code sets is required for entities covered by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). On April 1, 2014, the Protecting Access to Medicare Act of 2014 (Pub. L. No. 113-93) (PAMA) was enacted. Section 212 of PAMA, titled "Delay in Transition from ICD-9 to ICD-10 Code Sets," provides that "[t]he Secretary of Health and Human Services may not, prior to October 1, 2015, adopt ICD-10 code sets as the standard for code sets under section 1173(c) of the Social Security Act (42 U.S.C. 1320d-2(c)) and section 162.1002 of title 45, Code of Federal Regulations." As of now, the Secretary has not implemented this provision under HIPAA.

We are addressing the conversion of ICD-9-CM to ICD-10-CM codes for the IRF PPS in this final rule, but in light of PAMA, the effective date of those changes would be the date when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions. Until that time, we will continue to require use of the ICD-9-CM codes for the IRF PPS.

CMS, along with our support contractor 3M, has spent several years implementing a process for the transition from the use of ICD-9-CM diagnosis codes to ICD-10-CM codes within both the IRF PPS Grouper and the software for evaluating IRFs' compliance with the 60 percent rule. As

this will be the first time that ICD-10-CM codes have been used for the IRF PPS, we invited public comment in the proposed rule on our translation of the diagnosis code lists into ICD-10-CM.

To ensure a smooth transition from the use of ICD-9-CM diagnosis codes to ICD-10-CM codes for the IRF PPS and to allow for public comment on these lists, we proposed ICD-10-CM lists that were available for download from the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html>. The proposed ICD-10-CM code lists were intended to be used when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions. To convert these lists from ICD-9-CM to ICD-10-CM, we used the General Equivalence Mappings (GEMs) that were developed as a tool to assist in converting ICD-9-CM-based applications to ICD-10-CM. The GEMs tool is a comprehensive translation dictionary that was developed over a 3-year period by CMS and the Centers for Disease Control and Prevention (CDC), with input from both the American Hospital Association and the American Health Information Management Association (AHIMA). They can be used to translate any ICD-9-CM-based data into ICD-10-CM. For more information on GEMs, please refer to the General Equivalence Mappings Frequently Asked Questions Booklet, which is available for download from the CMS Web site at <http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html>. Like a translation dictionary, the GEMs tool is based on the complete meaning of a given code, where "meaning" refers to the correspondence between the official documents (tabular and index) that define each code set. The GEMs tool contains a complete and comprehensive bidirectional set of mappings between ICD-9-CM and ICD-10-CM.

Our intention in converting the ICD-9-CM diagnosis codes to ICD-10-CM diagnosis codes within the IRF PPS was for the converted codes to reflect the same "meaning" as the original codes. That is, except for the specific changes to the "Impairment Group Codes That Meet Presumptive Compliance Criteria" list and to the "ICD-9-CM Codes That Meet Presumptive Compliance Criteria" list described in section VIII of this final rule, we did not intend to add conditions to, or delete conditions from, the ICD-9-CM codes used in the IRF PPS. Thus, for all IRF lists containing an ICD-9-CM code, we used the 2014 GEMs, which can be downloaded from the CMS Web site at <http://>

www.cms.gov/Medicare/Coding/ICD10/2014-ICD-10-CM-and-GEMs.html to create a translation list, and then we reviewed and revised that translation list to ensure that all of the codes on the new ICD-10-CM list reflect as closely as possible the same "meaning" as the codes that were present on the old ICD-9-CM list.

The majority of ICD-9-CM codes have straightforward translation alternative(s) in ICD-10-CM, where the diagnoses classified to a given ICD-9-CM code are replaced by one or more ICD-10-CM codes. Wherever possible, we erred on the side of including a given ICD-10-CM code if we believed that a patient coded with that ICD-10-CM code would have been correctly coded with the associated ICD-9-CM prior to the transition from ICD-9-CM to ICD-10-CM. Our intent is that the meaning of the diagnosis codes is thereby unchanged because all of the patient records that would have been correctly coded using the ICD-9-CM codes are correctly coded using one or more of the specific ICD-10-CM codes. For example, the ICD-9-CM code 582.1, "Human herpesvirus 6 encephalitis," translates directly to the ICD-10-CM code B1001, "Human herpesvirus 6 encephalitis."

Below, we note two issues within ICD-10-CM coding that differ from ICD-9-CM coding, and therefore, require special attention to ensure correct coding of patient diagnoses under ICD-10-CM.

- *Combination Diagnosis Codes in ICD-9-CM and ICD-10-CM*—Both ICD-9-CM and ICD-10-CM contain diagnosis codes called combination codes, meaning that one code contains two or more diagnoses. Typically, one diagnosis in the combination code is a chronic disease, such as diabetes, and the other diagnosis is an associated manifestation or complication of the disease, such as diabetic nephropathy.

ICD-10-CM contains many new combination codes that are not contained in ICD-9-CM. In terms of a coded record, this means that the same diagnoses coded with one ICD-10-CM combination code may require two or more ICD-9-CM codes to capture a comparable level of detail. In addition, ICD-9-CM contains combination codes with diagnosis terminology that was revised or deleted from ICD-10-CM, with the result that the same diagnoses coded with one ICD-9-CM code may require two or more ICD-10-CM codes to capture a comparable level of detail. For example, ICD-9-CM code 115.11, "Infection by *Histoplasma duboisii*, meningitis" translates to a pair of ICD-10-CM codes, "B39.5—Histoplasmosis

duboisii” and code “G02—Meningitis in other infectious and parasitic diseases classified elsewhere.” In such instances, the intent of our policy is unchanged because the patient records that would have been correctly coded using the single ICD-9-CM code will now be correctly coded using a combination of ICD-10-CM codes. Furthermore, to maintain the same meaning and reflect the same diagnoses as the ICD-9-CM code in such instances, we require the patient’s IRF-PAI record to have all of the relevant combination of ICD-10-CM codes present to reflect the condition on the list. If only one of the ICD-10-CM codes required to reflect the condition on the list is included on the IRF-PAI, the record will not accurately reflect the same diagnoses as the ICD-9-CM code. We note that, in some cases, IRFs may need to use a combination of ICD-10-CM codes to represent an Etiologic Diagnosis on the IRF-PAI form. For this reason, we will add additional spaces to the Etiologic Diagnosis field (Item #22) on the IRF-PAI, effective October 1, 2015. The new draft IRF-PAI form for IRF discharges occurring on or after October 1, 2015, is available for download from the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html>.

• **Seventh Character Extensions in ICD-10-CM**—Certain codes in ICD-10-CM require the use of a seventh character in the code, where each seventh character of the code has one of the following meanings:

++ The seventh character “A” in the code indicates that the diagnosis is an initial encounter.

++ The seventh character “D” in the code indicates that the patient is receiving aftercare for the injury or illness.

++ The seventh character “S” in the code indicates that the patient no longer requires care for any aspect of the initial injury or illness itself, but that the patient is receiving care for a late effect of the injury or illness.

In the IRF PPS context, these seventh character extensions only apply to ICD-10-CM diagnosis codes related to certain types of injuries. The corresponding ICD-9-CM diagnosis codes currently listed on the “List of Comorbidities,” “ICD-9-CM Codes That Meet Presumptive Compliance Criteria,” and “Impairment Group Codes That Meet Presumptive Compliance Criteria” only map to the seventh character extensions of “A” and “S,” but not to the seventh character extension of “D,” using the GEMs tool. Thus, including codes under ICD-10-CM with the seventh character extension of “D”

would mean adding conditions to the lists that were not included on the lists under ICD-9-CM. As we indicated previously, we did not intend to add, delete, or alter the conditions included on these lists in transitioning from ICD-9-CM to ICD-10-CM. Thus, we are not including ICD-10-CM codes with the seventh character extension of “D” on the ICD-10-CM versions of the “List of Comorbidities,” “ICD-9-CM Codes That Meet Presumptive Compliance Criteria,” or “Impairment Group Codes That Meet Presumptive Compliance Criteria.” In the IRF context, we define the patient as having a current diagnosis requiring the use of the seventh character extension of “A” if the patient requires current treatment for the injury and if the diagnosis has a direct effect on the patient’s rehabilitation therapy program in the IRF.

In addition, ICD-10-CM injury codes specify that traumatic fractures are coded using the appropriate seventh character extension for an initial encounter, where each seventh character of the code has one of the following meanings:

- The seventh character “A” in the code indicates that the diagnosis is an initial encounter for closed fracture.
- The seventh character “B” in the code indicates that the diagnosis is an initial encounter for open fracture.
- The seventh character “C” in the code indicates that the diagnosis is an initial encounter for open fracture type IIIA, IIIB, or IIIC.

We used the GEMs tool and the guiding rationales described above to translate the following lists of ICD-9-CM diagnosis codes for the IRF PPS into lists of ICD-10-CM diagnosis codes:

• **List of Comorbidities**—This file contains the list of comorbidities (ICD-9-CM codes) that are used to determine placement in tiers within the IRF Grouper software. Placement in one of the higher-paying tiers, which is triggered by the presence of one of the comorbidities on this list, results in a higher prospective payment amount for the IRF.

• **ICD-9-CM Codes That Meet Presumptive Compliance Criteria**—This file contains the list of diagnoses (ICD-9-CM codes) that are used for determining presumptive compliance with the IRF 60 percent rule.

• **Impairment Group Codes That Meet Presumptive Compliance Criteria**—This file contains the list of IGCs that meet presumptive compliance criteria for the 60 percent rule. While the IGC codes themselves are not ICD-9-CM diagnosis codes, the file contains a list of Etiologic Diagnosis codes (ICD-9-CM codes) that are excluded from particular IGCs. That

is, a given IGC that would otherwise meet the presumptive compliance criteria will not meet such criteria if the patient has one of the “excluded” Etiologic Diagnoses for that IGC.

The converted ICD-10-CM code tables associated with each of these lists are available for download from the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html> in conjunction with this final rule.

We received 3 comments on our proposed translation of the lists into ICD-10-CM, effective when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions, which are summarized below.

Comment: One commenter expressed concern about using the GEMs tool as the only means of converting the diagnosis codes from ICD-9-CM to ICD-10-CM, as this commenter said that the GEMs tool is limited in its ability to capture all of the clinical nuances of the coding conversion. This commenter suggested some enhanced conversions related to specific codes.

Response: As we described in the proposed rule, we used the GEMs tool as our starting point in converting the ICD-9-CM codes to ICD-10-CM, but we also reviewed and revised the resulting translation list from GEMs to ensure that all of the codes on the new ICD-10-CM list reflect as closely as possible the same “meaning” as the codes that were present on the old ICD-9-CM list. Thus, we did not use the GEMs tool as the sole method of converting the codes, but instead started with the GEMs tool translation and then reviewed and revised the translated lists from a clinical perspective to ensure that we were appropriately capturing the clinical nuances of the ICD-9-CM to ICD-10-CM conversions. We appreciate the commenter’s specific suggestions regarding particular code translations, and we will carefully consider the suggestions in finalizing the ICD-10-CM lists for implementation when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions.

Comment: One commenter requested that we provide a crosswalk from ICD-9-CM to ICD-10-CM to assist IRFs in better understanding the specific diagnosis codes that will be used for the IRF PPS when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions.

Response: The GEMs tool already provides a crosswalk from ICD-9-CM to ICD-10-CM, and it is readily available

for download from the CMS Web site at <http://www.cms.gov/Medicare/Coding/ICD10/2014-ICD-10-CM-and-GEMs.html> for use by all providers. We believe that providing a crosswalk ourselves apart from the GEMs tool that already exists would potentially create added confusion.

Comment: One commenter expressed support for our proposal to use the GEMs tool to convert diagnosis codes from ICD-9-CM to ICD-10-CM, but indicated some specific ICD-10-CM codes that the commenter believed should be added to the various ICD-10-CM lists. The specific ICD-10-CM codes that this commenter suggested for inclusion on the lists are divided into 3 categories. The first category includes those ICD-10-CM codes that the commenter said they believe may represent inconsistencies between the GEMs tool conversion of ICD-9-CM codes and our proposed translation of those codes in the proposed ICD-10-CM code lists. The second and third categories contain ICD-10-CM diagnosis codes that represent clinical conditions that the commenter said they believe should be added to the ICD-10-CM Codes That Meet Presumptive Compliance Criteria and the List of Comorbidities, respectively, and that are not currently reflected on these same lists in ICD-9-CM.

Response: We appreciate the commenter's detailed analysis of the converted ICD-10-CM lists that were published on the CMS Web site in conjunction with the proposed rule, and the specific suggestions this commenter provided regarding codes that we may have inadvertently omitted from the lists. We will carefully consider all of the specific ICD-10-CM codes that the commenter noted to ensure that we do not inadvertently omit any ICD-10-CM codes that should be included based on the use of the GEMs tool and our subsequent review and revision of these ICD-10-CM codes to ensure that they reflect the same clinical meaning as the ICD-9-CM codes that are currently on the respective lists. However, as we indicated in the proposed rule, we do not intend to add conditions to, or delete conditions from, the ICD-10-CM Codes That Meet Presumptive Compliance Criteria or the List of Comorbidities in translating the codes from ICD-9-CM to ICD-10-CM. Thus, at this time, we will not add the ICD-10-CM codes that would add additional clinical conditions to the lists. However, we will take the commenter's suggestions into consideration for future rulemaking.

Final Decision: After carefully considering the comments that we

received on our proposed translation of the ICD-9-CM code lists into ICD-10-CM using the GEMs tool, we are finalizing the ICD-10-CM lists that are available for download from the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Data-Files.html> for use when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions.

XII. Revisions and Updates to the Quality Reporting Program for IRFs

A. Background and Statutory Authority

Section 3004(b) of the Affordable Care Act added section 1886(j)(7) to the Act, which requires the Secretary to implement a quality reporting program (QRP) for IRFs. This program applies to freestanding IRFs, as well as IRF units that are affiliated with acute care facilities, which includes critical access hospitals (CAHs).

Beginning in FY 2014, section 1886(j)(7)(A)(i) of the Act requires the reduction of the applicable IRF PPS annual increase factor, as previously modified under section 1886(j)(3)(D) of the Act, by 2 percentage points for any IRF that fails to submit data to the Secretary in accordance with requirements established by the Secretary for that fiscal year. Section 1886(j)(7)(A)(ii) of the Act notes that this reduction may result in the increase factor being less than 0.0 for a fiscal year, and in payment rates under subsection (j) for a fiscal year being less than such payment rates for the preceding fiscal year. Any reduction based on failure to comply with the reporting requirements is, in accordance with section 1886(j)(7)(B) of the Act, limited to the particular fiscal year involved. The reductions are not to be cumulative and will not be taken into account in computing the payment amount under subsection (j) for a subsequent fiscal year.

Section 1886(j)(7)(C) of the Act requires that each IRF submit data to the Secretary for quality measures specified by the Secretary. The required quality measure data must be submitted to the Secretary in a form, manner, and time specified by the Secretary.

The Secretary is generally required to specify measures that have been endorsed by the entity with a contract under section 1890(a) of the Act. This contract is currently held by the National Quality Forum (NQF), which is a voluntary consensus standard-setting organization. The NQF was established to standardize health care quality measurement and reporting through its

consensus development process. Additional information regarding NQF and its consensus development process is available at http://www.qualityforum.org/Measuring_Performance/Measuring_Performance.aspx.

We have adopted NQF-endorsed measures in our reporting programs. However, section 1886(j)(7)(D)(ii) of the Act provides that “[i]n the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) [of the Act], the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.”

Section 1886(j)(7)(E) of the Act requires the Secretary to establish procedures for making data submitted under the IRF QRP available to the public. The Secretary must ensure that each IRF is given the opportunity to review the data that is to be made public prior to the publication or posting of this data.

We seek to promote higher quality and more efficient health care for all patients who receive care in acute and post-acute care settings. Our efforts are, in part, effectuated by quality reporting programs coupled with the public reporting of data collected under those programs. The initial framework of the IRF QRP was established in the FY 2012 IRF PPS final rule (76 FR 47873).

B. Quality Measures Previously Finalized for and Currently Used in the IRF Quality Reporting Program

1. Measures Finalized in the FY 2012 IRF PPS Final Rule

In the FY 2012 IRF PPS final rule (76 FR 47874 through 47878), we adopted applications of 2 quality measures for use in the first data reporting cycle of the IRF QRP: (1) An application of Catheter-Associated Urinary Tract Infection (CAUTI) for Intensive Care Unit Patients (NQF#0138); and (2) an application of Percent of Residents with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678). We adopted applications of these 2 measures because neither of them, at the time, was endorsed by the NQF for the IRF setting. We also discussed our plans to propose a 30-Day All-Cause Risk-Standardized Post-IRF Discharge Hospital Readmission Measure.

2. Measures Finalized in the CY 2013 OPPS/ASC Final Rule

In the CY 2013 OPPS/ASC final rule (77 FR 68500 through 68507), we adopted:

- Updates to the CAUTI measure to reflect the NQF's expansion of this quality measure to the IRF setting, replacing our previous adoption of an application of the quality measure for the IRF QRP;
- A policy that would allow any quality measure adopted for use in the IRF QRP to remain in effect until the measure was actively removed, suspended, or replaced (and specifically applied this policy to the CAUTI and Pressure Ulcer measures that had already been adopted for use in the IRF QRP); and
- A subregulatory process to incorporate NQF updates to IRF quality measure specifications that do not substantively change the nature of the measure.

At the time of the CY 2013 OPPS/ASC final rule, the NQF had endorsed the Pressure Ulcer measure for the IRF setting, and retitled it to cover both residents and patients within Long-Term Care Hospitals (LTCH) and IRF settings, in addition to the Nursing Home/Skilled Nursing Facility setting. Although the quality measure had been expanded to the IRF setting, we concluded that it was not possible to adopt the NQF-endorsed measure Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678) because it is a risk-adjusted measure, and the "Quality Indicator" section of the IRF-PAI did not contain the data elements that would be needed to calculate a risk-adjusted quality measure. As a result, we decided to: (1) Adopt an application of the Pressure Ulcer measure that was a non-risk-adjusted Pressure Ulcer measure (numerator and denominator data only); (2) collect the data required for the numerator and the denominator using the then-current version of the IRF-PAI; (3) delay public reporting of Pressure Ulcer measure results until we could amend the IRF-PAI to add the data elements necessary for risk-adjusting the Pressure Ulcer measure, and then (4) adopt the NQF-endorsed version of the measure covering the IRF setting through rulemaking (77 FR 68507).

a. National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)

In the CY 2013 OPPS/ASC final rule, we adopted the current version of

NHSN CAUTI Outcome Measure (NQF #0138) (replacing an application of this measure that we initially adopted in the FY 2012 IRF PPS (76 FR 47874 through 47886)). The NQF-endorsed measure applies to the FY 2015 adjustments to the IRF PPS annual increase factor and all subsequent annual increase factors (77 FR 68504 through 68505).

Since the publication of the CY 2013 OPPS/ASC final rule, the NHSN CAUTI quality measure has not changed, and it remains an active part of the IRF QRP. Additional information about this measure can be found at <http://www.qualityforum.org/QPS/0138>. Our procedures for data submission for this measure have also remained the same. IRFs should continue to submit their CAUTI measure data to the Centers for Disease Control and Prevention (CDC) NHSN. Details regarding submission of IRF CAUTI data to the NHSN can be found at the NHSN Web site at <http://www.cdc.gov/nhsn/inpatient-rehab/index.html>.

b. Application of Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678)

In the CY 2013 OPPS/ASC final rule (77 FR 68500 through 68507), we adopted a non-risk-adjusted application of this measure using the 2012 version of the IRF-PAI.

3. Measures Finalized in the FY 2014 IRF/PPS Final Rule

For the FY 2016 adjustments to the IRF PPS annual increase factor, in addition to retaining the previously discussed CAUTI and Pressure Ulcer measures, we finalized the adoption of one new measure: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) (78 FR 47902 through 47921). In addition, for the FY 2017 adjustments to the IRF PPS annual increase factor, we adopted 3 quality measures: (1) All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Inpatient Rehabilitation Facilities; (2) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680); and (3) the NQF-endorsed version of Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678).

a. Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)

In the FY 2014 IRF PPS final rule (78 FR 47905 through 47906), we adopted the CDC developed Influenza

Vaccination Coverage among Healthcare Personnel (NQF #0431) quality measure that is currently collected by the CDC via the NHSN. This measure reports on the percentage of IRF health care personnel (HCP) who receive the influenza vaccination.

In the FY 2014 IRF PPS final rule, we finalized that the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure have its own reporting period to align with the influenza vaccination season, which is defined by the CDC as October 1 (or when the vaccine becomes available) through March 31. We further finalized that IRFs will submit their data for this measure to the NHSN (<http://www.cdc.gov/nhsn/>). The NHSN is a secure Internet-based healthcare-associated infection tracking system maintained by the CDC and can be utilized by all types of health care facilities in the United States, including IRFs. The NHSN collects data via a web-based tool hosted by the CDC. Information on the NHSN system, including protocols, report forms, and guidance documents, can be found at <http://www.cdc.gov/nhsn/>. NHSN will submit the HCP influenza vaccination adherence percentage data to CMS on behalf of the facility. We also finalized that for the FY 2016 adjustments to the IRF PPS annual increase factor, data collection will cover the period from October 1, 2014 (or when the vaccine becomes available), through March 31, 2015.

Details related to the use of the NHSN for data submission and information on definitions, numerator data, denominator data, data analyses, and measure specifications for the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure can be found at <http://www.cdc.gov/nhsn/inpatient-rehab/hcp-vacc/index.html>. Because IRFs are already using the NHSN for the submission of CAUTI measure data, the additional administrative burden related to data collection and submission for this measure under the IRF QRP should be minimal.

While IRFs can enter information in NHSN at any point during the influenza vaccination season for the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure, data submission is only required once per influenza vaccination season, unlike the CAUTI measure, which is the other quality measure finalized for the IRF QRP that utilizes the CDC NHSN. We finalized that the final deadline for data submission associated with this quality measure will be May 15th of each year.

Also, the data collection period for this quality measure is not 12 months, as with other measures, but is approximately 6 months (that is, October 1, or when the vaccine becomes available, through March 31 of the following year). This data collection period is applicable only to Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431), and is not applicable to any other IRF QRP measures, proposed or adopted, unless explicitly stated. The measure specifications for this measure can be found at <http://www.cdc.gov/nhsn/inpatient-rehab/hcp-vacc/index.html> and at <http://www.qualityforum.org/QPS/0431>.

b. All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge From Inpatient Rehabilitation Facilities (NQF #2502, Under Review at NQF; see http://www.qualityforum.org/All-Cause_Admissions_and_Readmissions_Measures.aspx)

In the FY 2014 IRF PPS final rule (78 FR 47906 through 47910), we adopted an All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Inpatient Rehabilitation Facilities. This quality measure estimates the risk-standardized rate of unplanned, all-cause hospital readmissions for cases discharged from an IRF who were readmitted to a short-stay acute care hospital or LTCH, within 30 days of an IRF discharge. We noted that this is a claims-based measure that will not require reporting of new data by IRFs and thus will not be used to determine IRF reporting compliance for the IRF QRP. Please note that this measure is not NQF-endorsed, but it was submitted by CMS to the NQF for review on February 5, 2014 (http://www.qualityforum.org/All-Cause_Admissions_and_Readmissions_Measures.aspx).

c. Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)

In the FY 2014 IRF PPS final rule (78 FR 47906 through 47911), we adopted

the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680) measure for the IRF QRP, and we will collect the data for this measure through the addition of data items to the “Quality Indicator” section of the IRF-PAI.

We also added the data elements needed for this measure, as an influenza data item set, to the “Quality Indicator” section of the IRF-PAI, and data for this measure will be collected using this revised version of the IRF-PAI. The revised IRF-PAI will become effective on October 1, 2014. These data elements are harmonized with data elements (O0250: Influenza Vaccination Status) from the Minimum Data Set (MDS) 3.0 and the LTCH CARE Data Set Version 2.01, and the specifications and data elements for this measure are available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html>.

For purposes of this quality measure, the influenza vaccination season takes place from October 1 (or when the vaccine becomes available) through March 31 each year. The measure calculation and public reporting of this measure (once public reporting is implemented) will also be based on the influenza vaccination season, starting on October 1 (or when the vaccine becomes available) and ending on March 31 of the subsequent year.

The IRF-PAI Training Manual indicates how providers should complete these items during the time period outside of the vaccination season (that is, prior to October 1, or when the vaccine becomes available, and after March 31 of the following year). The measure specifications for this measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680), can be found on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIQualityMeasures.html>. Additional

information on this measure can also be found at <http://www.qualityforum.org/QPS/0680>.

d. Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678)—Adoption of the NQF-Endorsed Version of This Measure

In the FY 2014 IRF PPS final rule (78 FR 47911 through 47912), we adopted the NQF-endorsed version of the Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678), with data collection beginning October 1, 2014, using the revised version of the IRF-PAI, for quality reporting affecting the FY 2017 adjustments to the IRF PPS annual increase factor and subsequent year annual increase factors. We noted in the rule that, until September 30, 2014, IRFs should continue to submit pressure ulcer data using the version of the IRF-PAI released on October 1, 2012, for the purposes of data submission requirements for the FY 2015 and FY 2016 adjustments to the annual IRF PPS increase factor.

In the FY 2014 IRF PPS final rule (78 FR 47912 through 47916), we also adopted a revised version of the IRF-PAI starting October 1, 2014, for the FY 2017 adjustments to the IRF PPS annual increase factor and subsequent year annual increase factors.

We received several comments and questions related to previously finalized measures and our current policies. While we greatly appreciate the commenters' views on such previously finalized measures and policies, we did not make any proposals relating to them in the FY 2015 IRF PPS proposed rule. As such, we will not address these comments in this final rule. However, we will consider all of these comments in future rulemaking and program development.

TABLE 8—QUALITY MEASURES FINALIZED IN THE FY 2014 IRF PPS FINAL RULE AFFECTING THE FY 2016 AND 2017 ADJUSTMENTS TO THE IRF ANNUAL INCREASE FACTORS AND SUBSEQUENT YEAR INCREASE FACTORS

NQF measure ID	Measure title
NQF #0431+	Influenza Vaccination Coverage among Healthcare Personnel.
NQF #0680*	Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay).
NQF #0678*	Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay)—Adoption of the NQF-Endorsed Version of this Measure.
NQF #2502**	All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Inpatient Rehabilitation Facilities.

+ Using the CDC NHSN.

* Using the IRF-PAI Version 1.2 that is effective on October 1, 2014; available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/IRF-PAI-FINAL-for-Use-Oct2014-updated-v4.pdf>.

** Not NQF-endorsed, currently under review by NQF. (See http://www.qualityforum.org/All-Cause_Admissions_and_Readmissions_Measures.aspx).

C. New IRF QRP Quality Measures Affecting the FY 2017 Adjustments to the IRF PPS Annual Increase Factor and Beyond

1. General Considerations Used for Selection of Quality Measures for the IRF QRP

In the FY 2014 IRF PPS final rule (78 FR 47094), we noted that the successful development of an IRF quality reporting program that promotes the delivery of high-quality health care services in IRFs is our paramount concern. We discussed several of the factors we had taken into account in selecting measures to propose and finalize. We do wish to note here that, in our measure selection activities for the IRF QRP, we must take into consideration input we receive from a multi-stakeholder group, the Measure Applications Partnership (MAP), which is convened by the NQF as part of a pre-rulemaking process that we have established and are required to follow under section 1890A of the Act. The MAP is a public-private partnership comprised of multi-stakeholder groups convened by the NQF for the primary purpose of providing input to CMS on the selection of certain categories of quality and efficiency measures, as required by section 1890A(a)(3) of the Act. By February 1 of each year, the NQF must provide MAP input to CMS. We have taken the MAP's input into consideration in selecting measures for this rule. Input from the MAP is located at https://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report_2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx. We also take into account national priorities, such as those established by the National Priorities Partnership (NPP) at http://www.qualityforum.org/Setting_Priorities/NPP/National_Priorities_Partnership.aspx, the HHS Strategic Plan at <http://www.hhs.gov/secretary/about/priorities/priorities.html>, the National Strategy for Quality Improvement in Health Care at <http://www.ahrq.gov/workingforquality/nqs/nqs2012annlrpt.pdf>, and the CMS Quality Strategy at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html>.

To the extent practicable, we have sought to adopt measures that have been endorsed by a national consensus organization, recommended by multi-stakeholder organizations, and developed with the input of providers, purchasers/payers, and other stakeholders.

For the FY 2017 adjustments to the IRF PPS annual increase factor, in addition to retaining the previously discussed CAUTI (NQF #0138), Pressure Ulcer, Patient Influenza Vaccination (NQF #0680), Healthcare Personnel Influenza Vaccination (NQF #0431), and Hospital Readmission (NQF #2502) quality measures, we proposed in the FY 2015 IRF PPS proposed rule (79 FR 26336 through 26338) to adopt two new quality measures: (1) National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716), and (2) National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717). These quality measures are discussed in more detail below.

a. National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716).

In the FY 2015 IRF PPS proposed rule (79 FR 26336 through 26337), we proposed to adopt the CDC-developed National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716). The MRSA measure is a measure of hospital-onset unique blood source MRSA laboratory-identified events among all inpatients in the facility. This measure was adopted by the Hospital Inpatient Quality Reporting (IQR) Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51630, 51645) for the FY 2015 payment determination, with data collection beginning on January 1, 2013. It was also adopted by the LTCH Quality Reporting (LTCHQR) Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50712 through 50717) for the FY 2017 payment determination, with data collection beginning on January 1, 2015. This measure is NQF-endorsed. We included the MRSA measure in the December 1, 2013 Measures under Consideration (MUC) list. The MAP conditionally supported the direction of this quality measure, noting that the measure is not ready for implementation and suggesting that we harmonize this measure with other infection measures. We respectfully disagree with the position of the MAP, as the MRSA measure is fully endorsed by the NQF for various settings, including the IRF setting, which speaks to its suitability

for use in that setting. Methicillin-resistant *Staphylococcus aureus* (*S. aureus*) infections are caused by a strain of *S. aureus* bacteria that has become resistant to antibiotics commonly used to treat *S. aureus* infections. Between 2003 and 2004, an estimated 4.1 million persons in the United States had nasal colonization with MRSA.¹ In addition, in 2005 there were an estimated 94,000 invasive MRSA infections in the United States, which were associated with an estimated 18,000 deaths.² Healthcare-associated MRSA infections occur frequently in patients whose treatment involves the use of invasive devices, such as catheters or ventilators.

Currently, there are 22 States that have implemented a MRSA Prevention Collaborative, and at least 15 states that have reporting mandates for MRSA bacteremia in NHSN.³ For Medicare populations, MRSA infection is associated with increased cost, hospital length of stay, morbidity, and mortality. MRSA infections can be a consequence of poor quality of care.^{4,5} Older adults and patients in health care settings are most vulnerable to MRSA infections, as these patients may have weakened immune systems. A recent study reported that 9.2 percent of patients without a history of MRSA tested positive for MRSA at the time of the IRF admission.⁶ We also recently analyzed IRF claims submitted to Medicare during CY 2009. According to our analysis, IRFs reported a total of 3,464 cases of MRSA in 2009, including cases either present on admission or acquired during the IRF stay ("present on admission" indicators for ICD-9 codes are not available on the IRF claims).⁷

¹ Gorwitz RJ, Kruszon-Moran D, McAllister SK, et al. Changes in the prevalence of nasal colonization with *Staphylococcus aureus* in the United States, 2001–2004. *J Infect Dis* 2008; 197: 1226–34.

² Department of Health and Human Services. National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination. Available at <http://www.hhs.gov/ash/initiatives/hai/infection.html>.

³ Centers for Disease Control and Prevention. State Has Implemented a MRSA Prevention Collaborative. Available at <http://www.cdc.gov/hai/stateplans/states-w-MRSA-collaborative.html>.

⁴ Centers for Disease Control and Prevention. People at Risk of Acquiring MRSA Infections. Available at <http://www.cdc.gov/mrsa/index.html>.

⁵ Centers for Disease Control and Prevention. Management of Multidrug-Resistant Organisms in Healthcare Settings, 2006. Available at <http://www.cdc.gov/hicpac/pdf/guidelines/MDROGuideline2006.pdf>.

⁶ Rabinowitz RP, Kufera JA, Makely MJ. A Hidden Reservoir of Methicillin-resistant *Staphylococcus aureus* and Vancomycin-resistant *Enterococcus* in Patients Newly Admitted to an Acute Rehabilitation Hospital. *Physical Medicine & Rehabilitation* 2012 (4):18–22.

⁷ Bernard SL, Dalton K, Lenfestey N F, Jarrett NM, Nguyen KH, Sorensen AV, Thaker S, West ND.

We believe it is important to collect data on MRSA infections acquired during the IRF stay, because MRSA infection is associated with increased cost, hospital length of stay, morbidity, and mortality.

In the FY 2015 IRF PPS proposed rule (79 FR 26336 through 26337), we proposed to use the CDC/NHSN data collection and submission framework for reporting of the MRSA measure. This is the same framework currently used for reporting the CAUTI (NQF #0138) and Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) quality measures. Details related to the procedures for using the NHSN for data submission and information on definitions, numerator data, denominator data, data analyses, and measure specifications for the MRSA measure can be found at <http://www.qualityforum.org/QPS/1716> and <http://www.cdc.gov/nhsn/inpatient-rehab/mdro-cdi/index.html>. For January 2012 through January 2013, an estimated 15 IRFs reported laboratory-identified MRSA event data into NHSN. We refer readers to section XI.B.3.a. of this final rule for more information on data collection and submission. We sought public comments on the National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) for the FY 2017 IRF PPS annual increase factor and subsequent years. Our responses to public comments on this measure are discussed in this section of the final rule.

Comment: Several commenters expressed support of our proposal to adopt the MRSA measure, citing the importance of focusing on outcomes, such as healthcare-associated infections, because they are meaningful to patients and because of their impact on provider behavior. One commenter noted, as stated above, that the measure is NQF-endorsed for the IRF setting. A few commenters expressed support for CMS's effort to align IRF QRP quality measures with measures in other quality reporting initiatives.

Response: We appreciate the commenters' support for this outcome measure and recognition of our efforts to adopt measures for the IRF QRP that emphasize high-priority patient safety concerns and harmonize measures across settings, when applicable.

Study to support a CMS Report to Congress: Assess feasibility of extending the hospital-acquired conditions—present on admission IPPS payment policy to non-IPPS payment environments. Prepared for the Centers for Medicare & Medicaid Services (CMS Contract No. HHSM-500-T00007). 2011.

Comment: Several commenters objected to the proposed MRSA healthcare-associated infection measure due to the low prevalence of MRSA in IRFs, indicating that the measure would not be a meaningful quality measure in IRFs. Several comments noted the MRSA measure received only "conditional support" from the MAP, and several commenters noted that it would add additional data collection burden.

Response: The MRSA measure is endorsed by the National Quality Forum for use in several settings, including IRFs. Because of the scope of the patient safety problem posed by MRSA to the IRF patient population, as discussed earlier in this section of the final rule, as well as its burden on the health care system, we continue to believe it is in the best interest of patients to adopt this measure for the IRF QRP in order to promote awareness and encourage implementation of MRSA control procedures in the IRF setting. The measure is on the list of NQF-endorsed measures and can be found on the NQF Web site at <http://www.qualityforum.org/QPS/1716>. We note that we have taken the MAP's input into consideration in selecting quality measures, as we are required to do under section 1890(a)(4) of the Act. However, we are not required to follow the MAP's recommendations, but to take them into account when selecting measures for proposal. In addition to MAP input, we take a variety of other factors into account in selecting measures. In this instance, for example, the MRSA measure is NQF-endorsed for the IRF setting, an indication that it is appropriate for IRF patients. In addition, this measure is appropriate in light of the fact that MRSA infection most commonly affects older adults in hospitals or in facilities with longer lengths of stay and is associated with increased costs, hospital length of stay, morbidity, and mortality. For the reasons listed above, we continue to believe that this measure is appropriate for IRF patients.

Comment: One commenter was concerned that it may be difficult to distinguish infections present on admission from those that are healthcare-associated infections. Several commenters expressed concern that adoption of this quality measure would lead to additional and inappropriate screening for these conditions when patients are admitted to an IRF, and one commenter noted a concern about antibiotic resistance.

Response: The definition of MRSA laboratory-identified (LabID) events—used in the measure we proposed,

National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716)—is provided in the measure specifications, which are posted on the NQF Web site at <http://www.qualityforum.org/QPS/1716>, and it specifically addresses attribution through categorization of MRSA LabID events based on date admitted to the facility and date specimen collected, as well as by the current date and prior dates of specimen collection. As specified in the measure, Community-Onset (CO) is a LabID event collected as an outpatient or an inpatient less than or equal to 3 days after admission to the facility (that is, days 1, 2, or 3 of admission), while Healthcare Facility-Onset (HO) is defined as a LabID event collected from a patient greater than 3 days after admission to the facility (that is, days 4 or later of admission). Data from emergency department and outpatient observation locations (that is, outpatient encounters) are also included in this reporting of CO and HO events, in order to ensure that events are accurately categorized and identified. The CO definition accounts for infections acquired outside the IRF setting, either in the community or in other health care settings.

Regarding the commenter's concern that adoption of this quality measure would lead to additional and inappropriate screening, per NHSN protocol, LabID events are to be reported only from specimens collected for clinical decision-making and never from screening or surveillance cultures. Because these required LabID events are to be reported only from MRSA blood specimens, they represent actual and serious infections that should be treated appropriately and according to physician decision, as MRSA bacteria should never be found in blood. Therefore, this reporting should not be a driver of inappropriate antibiotic use. Additionally, we believe it is imperative that we close the gap with respect to monitoring for this serious infection within the continuum of care. Because this measure has been finalized for several other health care settings (see the FY 2012 IPPS/LTCH PPS final rule (76 FR 51630, 51645) for IQR Program; FY 2014 IPPS/LTCH PPS final rule (78 FR 50712 through 50717) for the LTCHQR Program), we believe that requiring IRFs to monitor for MRSA infections is necessary and will help further improve the quality of care provided to patients receiving services across the continuum of care.

Comment: One commenter suggested collecting MRSA data for one year in

order to determine if the measure is valuable.

Response: We believe that this is unnecessary because quality measures already undergo maintenance review at regular intervals in order to evaluate the value of ongoing use of these measures. As noted above, it is important to collect data on MRSA infections acquired during the IRF stay because MRSA infections are associated with increased cost, hospital length of stay, morbidity, and mortality.

Final Decision: Having carefully considered the comments we received on the National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716), we are finalizing the adoption of this measure as proposed for use in the IRF QRP.

b. National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717)

In the FY 2015 IRF PPS proposed rule (79 FR 26337 through 26338), we proposed to adopt the CDC-developed National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) that is currently collected by the CDC via the NHSN. The CDI measure is a measure of hospital-onset CDI laboratory-identified events among all inpatients in the facility. This measure was adopted by the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51630 through 51631) for the FY 2015 payment determination, with data collection having begun on January 1, 2013. It was also adopted by the LTCHQR program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50712 through 50717) for the FY 2017 payment determination, with data collection beginning on January 1, 2015. This measure is NQF-endorsed. We included the CDI measure in the December 1, 2013 MUC list. The MAP supported this measure.⁸ CDI can cause a range of serious symptoms, including diarrhea, serious intestinal conditions, sepsis, and death.⁹ In the United States, CDI is

responsible for an estimated 337,000 infections and 14,000 deaths annually.¹⁰ According to the HHS National Action Plan to Prevent Health Care-Associated Infections, CDI rates have increased in recent years.¹¹ The CDC estimates that CDIs cost more than \$1 billion in additional health care costs each year.¹² In recent years, CDIs have become more frequent, more severe, and more difficult to treat. Mortality rates for CDIs are highest in elderly patients.¹³ Rates of CDI among hospitalized patients aged 65 years and older increased 200 percent between 1996 and 2009, while deaths related to CDIs increased 400 percent between 2000 and 2007, partly attributed to a stronger germ strain.¹⁴ Further, the emergence and continued rise of CDI as a leading cause of gastroenteritis hospitalizations and deaths, particularly in the elderly, has been documented.¹⁶ CDI is associated with increased patient care costs, hospital lengths of stay, morbidity, and mortality. CDI can be a consequence of poor quality of care for Medicare patients.¹⁷

Illness from CDI most commonly affects older adults in hospitals or in facilities with longer lengths of stay, where germs spread more easily,

www.jstor.org/stable/pdfplus/10.1086/511798.pdf?acceptTC=true.

¹⁰ Centers for Disease Control and Prevention. *Investigating Clostridium difficile Infections Across the U.S.* Available at: <http://www.cdc.gov/hai/eip/pdf/Cdiff-factsheet.pdf>.

¹¹ Department of Health and Human Services. National Action Plan to Prevent Health Care-Associated Infections: Roadmap to Elimination. Available at <http://www.hhs.gov/ash/initiatives/hai/infection.html>.

¹² Centers for Disease Control and Prevention. Making Health Care Safer: Stopping *C. difficile* Infections. Available at: <http://www.cdc.gov/VitalSigns/HAI/index.html>.

¹³ Centers for Disease Control and Prevention. *Investigating Clostridium difficile Infections Across the U.S.* Available at: <http://www.cdc.gov/hai/eip/pdf/Cdiff-factsheet.pdf>.

¹⁴ Centers for Disease Control and Prevention. QuickStats: Rates of Clostridium difficile Infection Among Hospitalized Patients Aged ≥65 Years,* by Age Group—National Hospital Discharge Survey, United States, 1996–2009. MMWR, 60(34); 1171. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6034a7.htm>.

¹⁵ Centers for Disease Control and Prevention. Making Health Care Safer: Stopping *C. difficile* Infections. Available at: <http://www.cdc.gov/VitalSigns/HAI/index.html>.

¹⁶ Aron J. Hall, Aaron T. Curns, L. Clifford McDonald, Umesh D. Parashar, and Ben A. Lopman. The Roles of Clostridium difficile and Norovirus Among Gastroenteritis-Associated Deaths in the United States, 1999–2007. *Clinical Infectious Diseases* 2012;55(2):216–23. Published by Oxford University Press on behalf of the Infectious Diseases Society of America 2012. DOI: 10.1093/cid/cis386.

¹⁷ Dubberke ER, Reske KA, Olsen MA, McDonald LC, Fraser VJ. Short- and long-term attributable costs of Clostridium difficile-associated disease in nonsurgical inpatients. *Clin Infect Dis* 2008; 46:497–504. Available at: <http://cid.oxfordjournals.org/content/46/4/497.long>.

antibiotic use is more common, and people are especially vulnerable to infection.¹⁸ Considering CDIs are increasing in all health care facilities, and the IRF population is highly vulnerable to CDI, it is important to measure these rates in IRFs.¹⁹ According to an analysis of ICD–9 codes reported on Medicare claims, IRFs reported 7,720 cases of CDI-associated disease in 2009.²⁰ Currently, the “present on admission” indicators for ICD–9 codes are not available on IRF claims. Therefore, we are unable to determine whether the 7,720 reported cases of CDI were present on admission or acquired during the IRF stay. There is evidence that CDIs are preventable, and therefore, surveillance and measuring infection rates is important to reducing infections and improving patient safety. Thirty-seven states have implemented a *C. difficile* Prevention Collaborative, and at least 15 states have reporting mandates for CDI LabID events in NHSN.²¹ The goal for the CDI measure is to collect and publicly report IRF data on CDIs so that IRFs will be better informed about the incidence of this condition and better equipped to prevent it.

In the FY 2015 IRF PPS proposed rule (79 FR 26337 through 26338), we proposed to use the CDC/NHSN data collection and submission framework for reporting of the NHSN Facility-Wide Inpatient Hospital-Onset CDI Outcome Measure (NQF #1717). This framework is currently used for reporting the CAUTI (NQF #0138) and Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measures. Details related to the procedures for using the NHSN for data submission and information on definitions, numerator data, denominator data, data analyses, and measure specifications for the NHSN Facility-Wide Inpatient Hospital-Onset CDI Outcome Measure (NQF #1717) can be found at <http://www.qualityforum.org/QPS/1717> and

¹⁸ Centers for Disease Control and Prevention. Frequently Asked Questions about Clostridium difficile for Healthcare Providers. Available at: http://www.cdc.gov/HAI/organisms/cdiff/Cdiff_faqs_HCP.html.

¹⁹ Marciniak C, Chen D, Stein A, et al. Prevalence of Clostridium Difficile Colonization at Admission to Rehabilitation. *Archives of Physical Medicine and Rehabilitation* 2006; 87(8):1086–1090.

²⁰ Bernard SL, Dalton K, Lenfestey N F, Jarrett NM, Nguyen KH, Sorensen AV, Thaker S, West ND. Study to support a CMS Report to Congress: Assess feasibility of extending the hospital-acquired conditions—present on admission IPPS payment policy to non-IPPS payment environments. Prepared for the Centers for Medicare & Medicaid Services (CMS Contract No. HHSM–500–T00007). 2011.

²¹ Centers for Disease Control and Prevention. State Has Implemented a *C. diff* Prevention Collaborative. Available at: <http://www.cdc.gov/hai/stateplans/states-w-CDI-collaborative.html>.

⁸ National Quality Forum. *Measure Applications Partnership Pre-Rulemaking Report: 2014 Recommendations of Measures Under Consideration by HHS: February 2014*. Available at: https://www.qualityforum.org/Publications/2014/01/MAP_Pre-Rulemaking_Report_2014_Recommendations_on_Measures_for_More_than_20_Federal_Programs.aspx.

⁹ McDonald LC, Coignard B, Dubberke E, et al. Recommendations for surveillance of Clostridium difficile-associated disease. *Infect Control Hosp Epidemiol* 2007;28:140–145. Available at: <http://>

<http://www.cdc.gov/nhsn/inpatient-rehab/mdro-cdi/index.html>.

We sought public comments on the National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset CDI Outcome Measure (NQF #1717) for the FY 2017 IRF PPS annual increase factor and subsequent years. The responses to public comments on this measure are discussed below in this section of the final rule.

Comment: Several commenters supported the CMS proposal to adopt the CDI measure, citing the importance of focusing on outcomes, such as healthcare-associated infections, because they are meaningful to patients and because it can impact provider behavior. One commenter supported the measure because it encourages hospitals to focus on prevention and appropriate treatment and has important implications for patient outcomes, society, and reduced health care expenditures. One commenter noted the measure is NQF-endorsed for the IRF setting, and two commenters expressed support for CMS's effort to align IRF QRP quality measures with measures in other quality reporting initiatives. A commenter who supports the measure suggested the significance of reporting CDIs is increased due to a higher than expected number of cases.

Response: We appreciate the commenters' support and recognition of the importance of the expansion of the IRF QRP to include this measure. *C. difficile* is a pathogen of serious concern, causing morbidity and mortality throughout the continuum of care. Transmission can only be controlled and infection prevented if monitoring occurs across the health care settings.

Comment: Several commenters objected to the proposed CDI measure due to the low prevalence of CDIs in IRFs, indicating that the measure would not be a meaningful quality measure in IRFs. One commenter noted that it adds additional data collection burden.

Response: The CDI measure is endorsed by the NQF for use in several settings, including the IRF setting. As with MRSA, because of the scope of the patient safety problem posed by CDI to the very vulnerable IRF population, as well as its burden on the health care system, we believe it is in the best interest of patients to adopt this measure to promote awareness and

encourage immediate implementation of CDI control procedures within the IRF setting. The measure is on the list of NQF-endorsed measures and can be found on the NQF Web site at <http://www.qualityforum.org/QPS/1717>. In addition, the MAP supported this quality measure for the IRF setting. This measure is appropriate in light of the fact that illness from CDI most commonly affects older adults in hospitals or in facilities with longer lengths of stay and is associated with increased costs, hospital length of stay, and those who have been treated with antibiotics. *C. difficile* is a pathogen of serious concern that causes patient morbidity and mortality throughout all health care settings. Furthermore, lack of monitoring for this serious infection in the IRF setting creates a monitoring gap within the continuum of care. Because this measure has been proposed and finalized for several other hospital settings, we believe that requiring IRFs to monitor for CDI is necessary and will help further improve the quality of care provided to Medicare beneficiaries. For all of the reasons we have discussed, we continue to believe this measure is appropriate for IRF patients.

Comment: One commenter was concerned that it may be difficult to distinguish infections present on admission from those that are hospital-acquired infections. The commenter expressed concern about inappropriate screening for these conditions if the quality measure was adopted.

Response: The definition of CDI LabID events, as provided in the measure specifications, which are posted on the NQF Web site at <http://www.qualityforum.org/QPS/1717>, specifically addresses attribution through categorization of CDI LabID events based on date admitted to the facility and date specimen collected, as well as by the current date and prior dates of specimen collection. As specified in the measure, Community-Onset (CO) is a LabID event collected as an outpatient or an inpatient less than or equal to 3 days after admission to the facility (that is, days 1, 2, or 3 of admission), while Community-Onset Healthcare Facility-Associated (CO-HCFA) is defined as a CO LabID event collected from a patient who was discharged from the facility within 4 weeks prior to current date of stool specimen collection. Data from emergency department and outpatient

observation locations (that is, outpatient encounters) are also included in this reporting of CO and HO events, in order to ensure that events are accurately categorized and identified. A Healthcare Facility-Onset (HO) is a LabID event collected more than 3 days after admission to the facility (that is, on or after day 4). The CDI measure is already in use in the hospital inpatient setting, where similar concerns have been raised and successfully addressed (see the FY 2012 IPPS/LTCH PPS final rule (76 FR 51630 through 51631) for the IQR program). We also note that the definition of CDI LabID events (as required by this measure) is based on laboratory testing and admission date data, and not clinical evaluation of the patient, allowing for a much less labor-intensive method to track CDIs. This provides an infection measure of CDI health care acquisition, exposure burden, and infection burden based almost exclusively on laboratory data and limited admission date data, including patient care location. LabID events use NHSN forms to collect all required data, using the definitions of each data field. Per NHSN protocol, LabID events are to be reported only from specimens collected for clinical decision-making (that is, collected from patients with greater than or equal to 3 unformed stools within 24 hours) and never from screening or surveillance cultures.

Final Decision: Having carefully considered the comments we received on the National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717), we are finalizing the adoption of this measure as proposed for use in the IRF QRP.

D. IRF QRP Quality Measures and Concepts Under Consideration for Future Years

We are considering whether to propose one or more of the quality measures and quality measure topics listed in Table 9 for future years in the IRF QRP. We invited public comment on these quality measures and quality measure topics, specifically the clinical importance of reported measure data, the feasibility of measure data collection and implementation, current use of reported measure data, and usefulness of the reported measure data to inform quality of care delivered to IRF patients.

TABLE 9—FUTURE MEASURES AND MEASURE TOPICS UNDER CONSIDERATION FOR PROPOSAL FOR THE IRF QUALITY REPORTING PROGRAM

National Quality Strategy Priority: Patient Safety:

Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674).

National Quality Strategy Priority: Patient and Caregiver-Centered Care:

Application of Percent of Residents Who Self-Report Moderate to Severe Pain (Short-Stay) (NQF #0676).

Not Endorsed/Under Development—IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients.

Not Endorsed/Under Development—IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients.

Not Endorsed/Under Development—IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients.

Not Endorsed/Under Development—IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients.

In particular, we are considering whether to propose one or more of the following measures for future year IRP PPS increase factors: (1) IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients; (2) IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients; (3) IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients; (4) IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients; (5) Application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674); and (6) Application of Percent of Residents Who Self-Report Moderate to Severe Pain (Short-Stay) (NQF #0676).

IRFs are designed to provide intensive rehabilitation services to patients. Patients seeking care in IRFs are those whose illness, injury, or condition has resulted in a loss of function, and for whom rehabilitative care is expected to help regain that function. Examples of conditions treated in IRFs include stroke, spinal cord injury, hip fracture, brain injury, neurological disorders, and other diagnoses characterized by loss of function.

Given that the primary goal of rehabilitation is improvement in functional status, IRF clinicians have traditionally assessed and documented patients' functional statuses at admission and discharge to evaluate the effectiveness of the rehabilitation care provided to individual patients, as well as the effectiveness of the rehabilitation unit or hospital overall. In addition, research results have found differences in IRF patients' functional outcomes, thus we believe there is an opportunity for improvement in this area. Differences in IRF patients' functional outcomes have been found by geographic region, insurance type, and race/ethnicity after adjusting for key patient demographic characteristics and admission clinical status. This supports the need to monitor IRF patients' functional outcomes. For example,

Reistetter²² examined discharge motor function and functional gain among IRF patients with stroke and found statistically significant differences in functional outcomes by U.S. geographic region, insurance type, and race/ethnicity group after risk adjustment. O'Brien and colleagues²³ found differences in functional outcomes across race/ethnicity groups in their analysis of Medicare assessment data for patients with stroke after risk adjustment. O'Brien and colleagues²⁴ also noted that the overall IRF length of stay decreased 1.8 days between 2002 and 2007 and that shorter IRF stays were significantly associated with lower functioning at discharge.

We are currently developing 4 functional status quality measures for the IRF setting:

(1) Quality Measure: IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients for Medical Rehabilitation Patients;

(2) Quality Measure: IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients for Medical Rehabilitation Patients;

(3) Quality Measure: IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients for Medical Rehabilitation Patients; and

(4) Quality Measure: IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients for Medical Rehabilitation Patients.

We invited public comment on our intent to propose these measures for the FY 2019 adjustments to the IRF PPS annual increase factor and subsequent

year increase factors. The draft measure specifications for these measures are posted at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Details.html>. The development of these measures is expected to be completed in 2014, at which time they will be submitted to the NQF, the entity with a contract under section 1890(a) of the Act, for review. Our responses to public comments on these quality measures are discussed in this section of the final rule.

Comment: Several comments were received about the quality measure Application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long-Stay) (NQF #0674). One commenter supported this measure. Several commenters opposed the measure, citing that the measure is not appropriate for the IRF setting and that it is unclear how a major fall is defined and what tool will be used to collect this data.

Response: We thank the commenters for their input and will take these comments into consideration to inform our ongoing measure development efforts for this measure and our ongoing consideration of the potential to adopt this measure in the IRF QRP through future rulemaking. For the purpose of this measure, "major injury" is defined as including bone fractures, joint dislocations, closed head injuries with altered consciousness, or subdural hematoma. If selected for proposal, and finalized through the future rulemaking process, for data collection purposes, we would revise the IRF PAI to include the items used for this quality measure, which are found in the Minimum Data Set version 3.0. We believe that this measure is appropriate for the IRF setting. Fall-related injuries are the most common cause of accidental death in people aged 65 years and older, resulting in approximately 41 fall-related deaths per 100,000 people per

²² Reistetter TA, Karmarkar AM, Graham JE, et al. Regional variation in stroke rehabilitation outcomes. *Arch Phys Med Rehabil*. 95(1):29–38, Jan. 2014.

²³ O'Brien SR, Xue Y, Ingersoll G, et al. Shorter length of stay is associated with worse functional outcomes for medicare beneficiaries with stroke. *Physical Therapy*. 93(12):1592–1602, Dec. 2013.

²⁴ O'Brien SR, Xue Y, Ingersoll G, et al. Shorter length of stay is associated with worse functional outcomes for medicare beneficiaries with stroke. *Physical Therapy*. 93(12):1592–1602, Dec. 2013.

year.^{25 26} In 2010, the total direct medical costs of fall injuries for people aged 65 years and older was \$30 billion. The annual direct and indirect cost of fall injuries is expected to reach \$54.9 billion by 2020.²⁷ Falls thus represent a significant cost burden to the entire health care system, with injurious falls accounting for 6 percent of medical expenses among those aged 65 years and older.²⁸ This measure was developed by CMS and is currently NQF-endorsed for the Nursing Home/Skilled Nursing Facility setting. Further, we adopted this measure for the LTCH Quality Reporting Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877). We included the Falls with Major Injury quality measure in the December 1, 2013 Measures Under Consideration (MUC) list, and the MAP conditionally supported this quality measure for the IRF setting. Additional information regarding NQF #0674, on which our application of the measure will be based, if proposed and adopted through future rulemaking process, is available at <http://www.qualityforum.org/QPS/0674>.

Comment: Several comments were received about the quality measure Application of Percent of Residents Who Self-Report Moderate to Severe Pain (Short-Stay) (NQF #0676). One commenter supported this measure. Several commenters opposed the measure, indicating that it is not appropriate for the IRF setting and does not take into account pain that may be a healthy part of a treatment protocol. One commenter opposed the measure because it was unclear when the assessment would be completed, noting that patients whose pain was inadequately assessed at a previous facility would be admitted to the IRF experiencing pain, and the commenter did not want pain present at the time of admission to be attributed to the IRF. This commenter also noted that it is not addressed how the self-report of pain would be conducted for cognitively impaired patients.

²⁵ L. Currie, *Chapter 10: Fall and Injury Prevention*. In: *Patient Safety and Quality: An Evidence-Based Handbook for Nurses* (Rockville: Agency for Healthcare Research and Quality, 2008).

²⁶ U.S. Department of Health & Human Services, "Implementation Guide to Prevention of Falls with Injury," http://www.dcha.org/wp-content/uploads/falls_change-package_508.pdf.

²⁷ Centers for Disease Control and Prevention, "Costs of Falls Among Older Adults," <http://www.cdc.gov/homeandrecreationalafety/falls/fallcost.html>.

²⁸ L. Z. Rubenstein, C. M. Powers, and C. H. MacLean, "Quality indicators for the management and prevention of falls and mobility problems in vulnerable elders," *Ann Intern Med* 135, no. 8 Pt 2 (2001).

Response: We thank the commenters for their input and will take these comments into consideration to inform our ongoing measure development efforts and our ongoing consideration of including this measure in the future.

Comment: Several commenters expressed strong support for functional status quality measures because functional improvement is a key focus of IRF care. The commenters noted several issues that CMS should consider in the development of these functional status quality measures, including NQF endorsement as well as the importance of adequate risk adjustment and specified exclusion criteria. Several commenters requested that CMS consider using the FIM[®] instrument as part of the quality measure. One commenter suggested expediting the development of the functional status quality measures.

Response: We appreciate the strong support for functional status measures in the IRF setting. The functional status quality measures are in development and will be submitted to NQF for consideration of endorsement in the fall. The draft quality measure specifications (version 2), including the inclusion and exclusion criteria, the risk adjustment variables and risk adjustment approach can be found on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Downloads/Draft-Specifications-for-the-Functional-Status-Quality-Measures-for-Inpatient-Rehabilitation-Facilities-Version-2.pdf>. We appreciate the commenters for their input on the quality measures and will take this feedback under consideration as we finalize the development of the IRF functional status quality measures.

Comment: Several commenters questioned CMS's future proposal of the self-care and mobility functional status quality measures due to their concern that the measures are not yet fully developed nor adequately risk adjusted.

Response: The functional status quality measures have been under development for more than 3 years. The steps in measure development have included analysis, technical expert panel review, and public posting of specifications with public input. Nearing their completion, we anticipate submission of the quality measures to the NQF for its review this fall. The current specifications for the self-care quality measure lists 41 risk adjusters, and the mobility quality measure list 43 risk adjusters. The risk adjusters were selected based on our review of the literature, input from the function

expert panel and feedback from public comments.

Comment: One commenter conveyed their concern regarding the use of the Continuity Assessment Record and Evaluation Tool (CARE Tool) as currently proposed, because the CARE Tool is not appropriate for data collection for the IRF setting.

Response: We interpret the commenter's comment to mean that they were concerned that we would use the CARE Tool as the data source for the functional status quality measures. We further interpret the commenter to mean that we would use the CARE Tool in its entirety for the collection of these measures because they believe that the use of the CARE Tool in its entirety would be inappropriate in an IRF. We would like to clarify that the functional status quality measures do not require data collection of the entire CARE Tool. The functional status measures were developed using a subset of the CARE Tool items (and their response codes), not the CARE Tool in its entirety. These particular assessment items (and response codes) used for the functional status measures, were derived from a subset of items within the CARE Tool which had been tested for reliability and validity in the IRF setting as part of the Post-Acute Payment Reform Demonstration (PAC PRD). A summary of the reliability and validity results are provided in the draft measure specifications posted at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Details.html>.

Comment: Several commenters conveyed concern related to undue burden associated with "double documentation" for the functional status quality measures.

Response: We interpret the comment to refer to the collection of both existing data elements and additional similar or redundant data elements. We appreciate the concerns related to any undue burden, including collection of both existing data elements and additional similar data elements, and take such concerns under consideration.

Comment: One commenter was concerned about relying on data from a demonstration that had flaws in data collection and testing, and wondered whether these quality measures will perform as intended.

Response: We interpreted the commenter's concern to be a concern about the validity of the CARE items tested as part of the PAC PRD. We further interpret their concern being related to the measures performing "as

intended” to imply that they wonder if the measures would be able to depict quality. We have described the development and the assessment of the CARE items and examined the validity and reliability of these CARE items in reports that summarize this work and these reports are posted on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/The-Development-and-Testing-of-the-Continuity-Assessment-Record-and-Evaluation-CARE-Item-Set-Final-Report-on-the-Development-of-the-CARE-Item-Set-and-Current-Assessment-Comparisons-Volume-3-of-3.pdf> and <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/The-Development-and-Testing-of-the-Continuity-Assessment-Record-and-Evaluation-CARE-Item-Set-Final-Report-on-the-Development-of-the-CARE-Item-Set-Volume-1-of-3.pdf>. We anticipate that the quality measures will perform as intended and that they will provide information pertaining to quality due to the rigor applied in the development of the measures, including the risk adjustment variables used in measure calculation. In addition, we intend to perform ongoing analysis of the performance of the measures as part of our obligation as a quality measure steward.

Comment: We received several comments pertaining to concerns surrounding the ability of the quality measures to capture small, but important levels of functional change, specifically concerns related to “floor and ceiling effects.”

Response: We interpret the commenter to mean that “floor and ceiling effects” pertain to the assessment items used in the measure not being able to capture change for patients who would fall at the lower or upper ends of the measurement scale. We appreciate concerns related to any instrument that would have limitations such as these floor and ceiling effects. In the development of these quality measures this major concern was taken under consideration, and there was a focus on including items that would cover a wide range of functioning, thus minimizing limitations in measuring change for patients who are low functioning and patients who are high functioning. Details about the development of the CARE items can be

found on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Downloads/Draft-Specifications-for-the-Functional-Status-Quality-Measures-for-Inpatient-Rehabilitation-Facilities-Version-2.pdf>.

Comment: Several commenters indicated concerns about the need for standardized training to ensure inter-rater reliability for the CARE function items and noted that this training would add additional burden to facilities.

Response: We appreciate the commenters’ concerns related to data collection and the requirements that accompany the implementation of new quality measures and have addressed this in the past with public outreach including training sessions, webinars, open door forums, and help desk support.

E. Timeline for Data Submission for New IRF QRP Quality Measures Affecting the FY 2017 Adjustments to the IRF PPS Annual Increase Factor

In the FY 2015 IRF PPS proposed rule (79 FR 26339), we proposed the following data submission timeline for the quality measures for the FY 2017 adjustments to the IRF PPS annual increase factor. We proposed that IRFs would be required to submit data on admissions and discharges occurring between January 1, 2015, and December 31, 2015 (CY 2015), for the FY 2017 adjustments to the IRF PPS annual increase factor. We proposed this time frame because we believe this will provide sufficient time for IRFs and CMS to put processes and procedures in place to meet the additional quality reporting requirements. Given these measures are collected through the CDC’s NHSN, and IRFs are already familiar with the NHSN reporting system, as they currently report the CAUTI measure, we believe this time frame will allow IRFs ample opportunity to begin reporting the MRSA and CDI measures. We also proposed the quarterly data submission deadlines for the FY 2017 adjustments to the IRF PPS annual increase factor to occur approximately 135 days after the end of each quarter, as outlined in the Table 10. Each quarterly deadline would be the date by which all data collected during the preceding quarter would be required to be submitted to us for measures using the IRF-PAI and to the CDC for measures using the NHSN. We invited public comment on these proposed timelines for data submission

for the proposed IRF QRP quality measures for the FY 2017 adjustments to the IRF PPS annual increase factor.

Comment: Several commenters recommended that CMS delay the adoption of the National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716), because it is not ready for implementation. They recommended additional education and training as well as additional testing should be conducted before implementation.

Response: As the MRSA quality measure is already NQF-endorsed for the IRF setting, we do not believe that additional testing is required before implementation. By utilizing CDC’s NHSN for MRSA reporting, we are building upon IRFs’ ongoing experience with data reporting via the NHSN. Quality measures undergo maintenance review at regular intervals in order to evaluate the value of ongoing use of these measures.

Comment: Several commenters recommended that CMS delay the adoption of the National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717), because it is not ready for implementation. They recommended additional testing should be conducted before implementation.

Response: As the CDI quality measure is NQF-endorsed for the IRF setting, we do not believe that additional testing is required before implementation. By utilizing CDC’s NHSN for CDI reporting, we are building upon IRFs’ ongoing experience with data reporting via the NHSN, but recognize that additional education and training would be helpful.

Final Decision: After careful consideration of the comments we received, we are finalizing our proposal to begin to submit data for the MRSA and CDI measures on admissions and discharges starting January 1, 2015, including the quarterly submission deadlines. While we have taken into consideration comments suggesting that we delay implementation of these measures, we do not believe we can delay closing the monitoring gap that would continue to exist if we delayed implementation of these important measures. Adjustments to the IRF PPS annual increase factor for the MRSA and CDI measures will begin with FY 2017.

TABLE 10—TIMELINES FOR SUBMISSION OF IRF QRP QUALITY DATA USING CDC/NHSN FOR FY 2017 ADJUSTMENTS TO THE IRF PPS ANNUAL INCREASE FACTOR: NATIONAL HEALTH SAFETY NETWORK (NHSN) FACILITY-WIDE INPATIENT HOSPITAL-ONSET METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA) BACTEREMIA OUTCOME MEASURE (NQF #1716) AND NATIONAL HEALTHCARE SAFETY NETWORK (NHSN) FACILITY-WIDE INPATIENT HOSPITAL-ONSET CLOSTRIDIUM DIFFICILE INFECTION (CDI) OUTCOME MEASURE (NQF #1717) *

Quarter	CDC/NHSN data collection period	CDC/NHSN data submission deadline
FY 2017 Increase Factor		
Quarter 1	January 1, 2015–March 31, 2015	August 15, 2015.
Quarter 2	April 1, 2015–June 30, 2015	November 15, 2015.
Quarter 3	July 1, 2015–September 30, 2015	February 15, 2016.
Quarter 4	October 1, 2015–December 31, 2015	May 15, 2016.

* The quarterly deadlines provided in this table apply to the CDC/NHSN data only. Timelines for submission of IRF–PAI data for the IRF PPS and Quality Indicator items are provided separately.

TABLE 11—SUMMARY OF IRF QRP MEASURES AFFECTING THE FY 2017 ADJUSTMENTS TO THE IRF PPS ANNUAL INCREASE FACTOR AND SUBSEQUENT YEAR INCREASE FACTORS

Continued IRF QRP Measure Affecting the FY 2015 Adjustments to the IRF PPS Annual Increase Factor and Subsequent Year Increase Factors:

- NQF #0138: National Health Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.*

Continued IRF QRP Measure Affecting the FY 2016 Adjustments to the IRF PPS Annual Increase Factor and Subsequent Year Increase Factors:

- NQF #0431: Influenza Vaccination Coverage among Healthcare Personnel.*

Continued IRF QRP Measures Affecting the FY 2017 Adjustments to the IRF PPS Annual Increase Factor and Subsequent Year Increase Factors:

- NQF #2502: All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Inpatient Rehabilitation Facilities.^**
- NQF #0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay).*
- NQF #0678: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay).*

New IRF QRP Measures Affecting the FY 2017 Adjustments to the IRF PPS Annual Increase Factor and Subsequent Year Increase Factors:

- NQF #1716: National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.
- NQF #1717: National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure.

+ Using CDC/NHSN.

* Using the IRF–PAI effective October 1, 2014.

^ Medicare Fee-for-Service claims data.

** This measure is under review at NQF (http://www.qualityforum.org/All-Cause_Admissions_and_Readmissions_Measures.aspx).

F. Timing for New IRFs To Begin Reporting Quality Data Under the IRF QRP Affecting the FY 2017 Adjustments to the IRF PPS Annual Increase Factor and Beyond

In the FY 2015 IRF PPS proposed rule (79 FR 26340 through 26341), we proposed that for the FY 2017 adjustments to the IRF PPS annual increase factor and subsequent year increase factors, that new IRFs be required to begin reporting quality data under the IRF QRP by no later than the first day of the calendar quarter subsequent to the quarter in which they have been designated as operating in the CASPER system. We invited public comment on this proposed timing for new IRFs to begin reporting quality data under the IRF QRP.

Comment: We did not receive any comments on the above proposal.

Final Decision: We are finalizing our policy regarding the timing for new IRFs to begin reporting quality data under the IRF QRP affecting the FY 2017

adjustments to the IRF PPS annual increase factor and beyond, as proposed.

G. IRF QRP Reconsideration and Appeals Procedures for the FY 2016 Adjustments to the IRF PPS Annual Increase Factor and Beyond

1. IRF QRP Reconsideration and Appeals for the FY 2014 and FY 2015 Adjustments to the IRF PPS Annual Increase Factor

In the FY 2014 IRF PPS final rule (78 FR 47919), we finalized a voluntary process that allowed IRF providers the opportunity to seek reconsideration of our initial noncompliance decision for the FY 2014 and FY 2015 adjustments to the IRF PPS annual increase factor. We stated that we would notify IRFs found to be noncompliant with the IRF QRP reporting requirements that they may be subject to the 2-percentage point reduction to their IRF PPS annual increase factor. The purpose of this notification is to put the IRF on notice of the following: (1) That the IRF has

been identified as being noncompliant with the IRF QRP reporting requirements for a given reporting period; (2) that the IRF will be scheduled to receive a 2-percentage point reduction to its IRF PPS annual increase factor for the applicable fiscal year; (3) that the IRF may file a request for reconsideration if it believes that the finding of noncompliance is erroneous, or that if it was noncompliant, it had a valid and justifiable excuse for this noncompliance; and (4) that, to receive reconsideration, the IRF must follow a defined process on how to file a request for reconsideration, which will be described in the notification. This defined process for filing a request for reconsideration was described on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Reconsideration-and-Disaster-Waiver-Requests.html>.

We further stated that upon the conclusion of our review of each request

for reconsideration, we would render a decision. We may reverse our initial finding of noncompliance if: (1) The IRF provides adequate proof of full compliance with all IRF QRP reporting requirements during the reporting period; or (2) the IRF provides adequate proof of a valid or justifiable excuse for noncompliance if the IRF was not able to comply with the requirements during the reporting period. We will uphold our initial finding of noncompliance if the IRF cannot show any justification for noncompliance.

If an IRF is dissatisfied with either our initial finding of noncompliance or a CMS decision rendered at the reconsideration level, it can appeal the decision with the Provider Reimbursement Review Board (PRRB) under 42 CFR part 405, subpart R. We recommended, however, that IRF providers submit requests for reconsideration to us before submitting appeals to the PRRB. We noted that this order of appeals has had good success under other established quality reporting programs and, from an IRF perspective, it allows for the opportunity to resolve issues earlier in the process, when we have dedicated resources to consider all reconsideration requests before payment changes are applied to the IRF's annual payment.

2. IRF QRP Program Reconsideration and Appeals Procedures for the FY 2016 Adjustments to the IRF PPS Annual Increase Factor and Beyond

In the FY 2015 IRF PPS proposed rule (79 FR 26340 through 26341), we proposed, for the FY 2016 adjustments to the IRF PPS annual increase factor and subsequent year increase factors, to adopt an updated process, as described below, that will enable an IRF to request a reconsideration of our initial noncompliance decision in the event that an IRF believes that it was incorrectly identified as being subject to the 2-percentage point reduction to its IRF PPS annual increase factor due to noncompliance with the IRF QRP reporting requirements for a given reporting period.

For the FY 2016 adjustments to the IRF PPS annual increase factor and subsequent year increase factors, we proposed that an IRF would receive a notification of noncompliance if we determine that the IRF did not submit data in accordance with section 1886(j)(7)(C) of the Act for the applicable fiscal year, and therefore, that the IRF is subject to a 2-percentage point reduction in the applicable IRF PPS annual increase factor as required by section 1886(j)(7)(A)(i) of the Act. We will only consider requests for

reconsideration once a provider has been found to be noncompliant and not before. IRFs will have 30 days from the date of the initial notification of noncompliance to review the CMS determination and submit to us a request for reconsideration. This proposed time frame allows us to balance our desire to ensure that IRFs have the opportunity to request reconsideration with our need to complete the reconsideration process and provide IRFs with our decision in a timely manner. Notifications of noncompliance and any subsequent notifications from CMS will be sent via a traceable delivery method such as certified U.S. mail or registered U.S. mail. We will not accept any requests for reconsideration that are submitted after the 30-day deadline.

We further proposed that as part of the IRF's request for reconsideration, the IRF will be required to submit all supporting documentation and evidence demonstrating (1) full compliance with all IRF QRP reporting requirements during the reporting period or (2) a valid or justifiable excuse for noncompliance if the IRF was not able to comply with the requirements during the reporting period. We will be unable to review any reconsideration request that fails to provide the necessary documentation and evidence along with the request. The documentation and evidence may include copies of any communications that demonstrate its compliance with all IRF QRP reporting requirements, as well as any other records that support the IRF's rationale for seeking reconsideration. A sample list of the proposed acceptable supporting documentation and evidence, as well as instructions for IRF providers to retrieve copies of the data submitted to CMS for the appropriate program year, can be found on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Reconsideration-and-Disaster-Waiver-Requests.html>.

We proposed that providers may withdraw reconsideration requests at any time and may file new requests within the proposed 30-day deadline. We also proposed that, in very limited circumstances, we may extend the proposed deadline for submitting reconsideration requests. It will be the responsibility of a provider to request an extension and demonstrate that extenuating circumstances existed that prevented the filing of the reconsideration request by the proposed deadline. We will not respond to any other types of requests, such as requests for administrative review of the

methodology and standards that determine the quality reporting requirements.

We proposed that an IRF provider wishing to request a reconsideration of our initial noncompliance determination will be required to do so by submitting an email to the following email address:

IRFQRPReconsiderations@cms.hhs.gov. Any request for reconsideration submitted to us by an IRF will be required to follow the guidelines outlined on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Reconsideration-and-Disaster-Waiver-Requests.html>. Following receipt of a request for reconsideration, we will provide—

- An email acknowledgment, using the contact information provided in the reconsideration request, to the CEO or CEO-designated representative that the request has been received; and

- Once we have reached a decision regarding the reconsideration request, an email to the IRF CEO or CEO-designated representative, using the contact information provided in the reconsideration request, regarding our decision.

We proposed to require any IRF that believes it was incorrectly identified as being subject to the 2-percentage point reduction to its IRF PPS annual increase factor to submit a request for reconsideration and receive a decision on that request before the IRF can file an appeal with the PRRB, as authorized by the Administrative Procedure Act. If the IRF is dissatisfied with the decision rendered at the reconsideration level, the IRF can appeal the decision with the PRRB under § 405.1835. We believe this proposed process is more efficient and less costly for us and for IRFs because it decreases the number of PRRB appeals by resolving issues earlier in the process. Additional information about the reconsideration process including requirements for submitting reconsideration request is posted on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Reconsideration-and-Disaster-Waiver-Requests.html>. We invited public comment on the proposed procedures for reconsideration and appeals. The responses to the public comments we received on this proposal are discussed below.

Comment: Several commenters supported the proposal to continue the reconsideration process for FY 2016.

Response: We thank the commenters for taking the time to express their support.

Comment: One commenter supported the reconsideration process, but believed that it should be expanded to include reconsideration of the results of the data validation process described in section XII.K. of this final rule. Specifically, if two clinicians do not document the patient's condition in the same way, but the rationale for the difference can be explained through the reconsideration and appeals process, then the provider should be allowed to use this process.

Response: We thank the commenter for their support of the proposed reconsideration process. We believe the current reconsideration process could be utilized for reconsideration of the results of the validation process, as long as all of the supporting documentation necessary for the request for reconsideration was previously submitted at the time of validation (that is, as long as the reconsideration request was based on the same documentation that was submitted for validation).

Final Decision: Having carefully considered the comments we received on the IRF QRP Reconsideration and Appeals procedures for the FY 2016 adjustments to the IRF PPS annual increase factor and beyond, we are finalizing this policy as proposed.

H. IRF QRP Data Submission Exception or Extension Requirements for the FY 2017 Adjustments to the IRF PPS Annual Increase Factor and Beyond

In the FY 2015 IRF PPS proposed rule (79 FR 26341 through 26342), for the IRF QRP's data submission exception or extension requirements for the FY 2017 adjustments to the IRF PPS annual increase factor and subsequent year increase factors, we proposed to continue using the IRF QRP's disaster waiver requirements that were adopted in the FY 2014 IRF PPS final rule (78 FR 47920) for the FY 2015 adjustments to the IRF PPS annual increase factor and subsequent year increase factors, which are outlined in this section, with the exception that the phrase "exception or extension" will be substituted for the word "waiver." We also proposed, for the FY 2017 adjustments to the IRF PPS annual increase factor and subsequent year increase factors, that we may grant an exception or extension to IRFs if we determine that a systemic problem with one of our data collection systems directly affected the ability of the IRF to submit data. Because we do not anticipate that these types of systemic errors will happen often, we do not anticipate granting an exception or

extension on this proposed basis frequently. We proposed that if we make the determination to grant an exception or extension, we will communicate this decision through routine communication channels to IRFs and vendors, including, but not limited to, issuing memos, emails, and notices on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html>.

In the FY 2014 IRF PPS final rule (78 FR 47920), we finalized a process for IRF providers to request and for us to grant exceptions or extensions for the quality data reporting requirements of the IRF QRP for one or more quarters, beginning with the FY 2015 adjustments to the IRF PPS annual increase factor and subsequent year increase factors, when there are extraordinary circumstances beyond the control of the provider.

In the event that an IRF seeks to request an exception or extension for quality reporting purposes, the IRF must request an exception or extension within 30 days of the occurrence of an extraordinary event by submitting a written request to CMS via email to the IRF QRP mailbox at IRFQRPReconsiderations@cms.hhs.gov. Exception or extension requests sent to us through any other channel will not be considered as a valid request for an exception or extension from the IRF QRP reporting requirements for any adjustment to the IRF PPS annual increase factor. The written request must contain all of the finalized requirements in the FY 2014 IRF PPS final rule (78 FR 47920) and on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Reconsideration-and-Disaster-Waiver-Requests.html>. When an exceptions or extension is granted, an IRF will not incur payment reduction penalties for failure to comply with the requirements of the IRF QRP, for the time frame specified by CMS. If an IRF is granted an exception, we will not require that the IRF submit any quality data for a given period of time. If we grant an extension to an IRF, the IRF will still remain responsible for submitting quality data collected during the time frame in question, although we will specify a revised deadline by which the IRF must submit this quality data. It is important to note that requesting an exception or extension from the requirements of the IRF QRP is separate and distinct from the purpose and requirements of § 412.614, which outline the requirements to follow if an

IRF is requesting a waiver regarding consequences of failure to submit complete and timely IRF-PAI payment data specified in that regulation. IRFs that have filed and were granted an IRF-PAI waiver in accordance with § 412.614 may so indicate when requesting an exception or extension from the IRF QRP requirements, but the submission of an IRF-PAI waiver request pursuant to § 412.614 will not be considered a valid request for an exception or extension from the IRF QRP requirements. To request an exception or extension from the IRF QRP requirements, the previously discussed process must be followed.

Additionally, in the FY 2014 IRF PPS final rule (78 FR 47920), we finalized a policy that allowed us to grant waivers (which we are now calling exceptions or extensions) to IRFs that have not requested them if we determine that an extraordinary circumstance, such as an act of nature, affects an entire region or locale. We stated that if this determination was made, we will communicate this decision through routine communication channels to IRFs and vendors, including, but not limited to, issuing memos, emails, and notices on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html>.

We invited public comment on these proposals regarding the IRF QRP's data submission exception or extension requirements for the FY 2017 adjustments to the IRF PPS annual increase factor and subsequent year increase factors. The responses to the public comments we received on this proposal are discussed below.

Comment: Several commenters supported the proposed Exception/Exemption waiver proposal.

Response: We thank the commenters for taking time to express their support.

Final Decision: Having carefully considered the comments we received on the proposed IRF QRP data submission exception or extension requirements for the FY 2017 adjustments to the IRF PPS annual increase factor and beyond, we are finalizing these requirements, as proposed.

I. Public Display of Quality Measure Data for the IRF QRP

Under section 1886(j)(7)(E) of the Act, the Secretary is required to establish procedures for making data submitted under the IRF QRP available to the public. Section 1886(j)(7)(E) of the Act also requires these procedures to ensure that each IRF provider has the

opportunity to review the data that is to be made public for its facility, prior to such data being made public. Section 1886(j)(7)(E) of the Act requires the Secretary to report quality measures that relate to services furnished in IRFs on the CMS Web site at <http://www.cms.hhs.gov/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/>.

Currently, the Agency is developing plans regarding the implementation of these provisions. We appreciate the need for transparency into the processes and procedures that will be implemented to allow for the public reporting of the IRF QRP data and to afford providers the opportunity to preview that data before it is made public. At this time, we have not established procedures or timelines for public reporting of data, but we intend to make the public aware of our strategy in the future. We invited public comments on what we should consider when developing future proposals related to public reporting. Our responses to the public comments we received on this topic are discussed below.

Comment: Several commenters encouraged CMS to report IRF quality data on Hospital Compare in the same manner that it reports data for acute care hospitals. One commenter encouraged CMS to report on IRF quality data as soon as possible.

Response: We thank the commenters for taking the time to express these views and suggestions regarding public reporting and will take them into consideration for future public reporting development.

J. IRF QRP Data Completion Thresholds for the FY 2016 Adjustments to the IRF PPS Annual Increase Factor and Beyond

Beginning in FY 2014, section 1886(j)(7)(A)(i) of the Act requires the reduction of the applicable IRF PPS annual increase factor, as previously modified under section 1886(j)(3)(D) of the Act, by 2 percentage points for any IRF that fails to submit data on quality measures specified by the Secretary in accordance with the form and manner specified by the Secretary for that fiscal year. To date, we have not established a standard for compliance other than for IRF providers to submit all applicable required data for all finalized IRF QRP quality measures, by the previously finalized quarterly deadlines. We have also specifically required monthly submission of such quality data for the healthcare-associated infection or vaccination data, which is reported to the CDC. In the FY 2015 IRF PPS proposed rule (79 FR 26342 through

26343), in reaction to the input received from our stakeholders seeking additional specificity related to required IRF QRP compliance affecting FY annual increase factor determinations and, due to the importance of ensuring the integrity of quality data submitted to CMS, we proposed to set specific IRF QRP thresholds for completeness of provider quality data beginning with data affecting the FY 2016 annual increase factor determination and beyond.

The IRF QRP, through the FY 2012 IRF PPS final rule, CY 2013 OPPI/ASC final rule, and FY 2014 IRF PPS final rule, requires providers to submit quality data using 2 separate data collection/submission mechanisms: Measures collected using the quality indicator section of the IRF-PAI are submitted through the CMS Quality Improvement Evaluation System (QIES); and measures stewarded by the Centers for Disease Control and Prevention (CDC) (Healthcare-associated Infection (HAI) measures and vaccination measures) are submitted using the CDC's National Healthcare Safety Network (NHSN). While we have previously finalized a claims-based measure (All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Inpatient Rehabilitation Facilities), such measures do not require IRFs to actually submit quality data to us, as they are calculated using claims data submitted to us for payment purposes. Thus, with claims-based measures, there is no quality data to which we could apply the proposed data completion thresholds. To ensure that IRF providers are meeting an acceptable standard for completeness of submitted data, we proposed that for the FY 2016 annual increase factor and beyond, IRF providers must meet or exceed two separate program thresholds: One threshold for quality measures data collected using the quality indicator section of the IRF-PAI and submitted through QIES; and a second threshold for quality measures data collected and submitted using the CDC's NHSN. We proposed that IRFs must meet or exceed both thresholds discussed below to avoid receiving a 2 percentage point reduction to their IRF PPS annual increase factor for a given FY, beginning with FY 2016, which considers quality data submitted during CY 2014. We proposed to hold IRF providers accountable for two different data completion thresholds for each of the 2 data submission mechanisms: A 95 percent data completion threshold for data collected using the quality indicator items on the IRF-PAI and

submitted through QIES; and a 100 percent threshold for data collected and submitted through the CDC's NHSN. We have chosen to hold providers to the lower threshold of 95 percent for the quality indicator items on the IRF-PAI, as there has to be some margin for error related to IRF patients that have been discharged emergently or against medical advice, as these situations make it more difficult to collect and submit the mandatory IRF-PAI quality indicator items at discharge. We do not believe the same impediments exist for the infection, vaccination, or other quality measures data that IRFs submit to the CDC's NHSN.

1. IRF QRP Completion Threshold for the Required Quality Indicator Data Items on the IRF-PAI

The quality indicator section of the IRF-PAI is composed of data collection items designed to inform quality measure calculations, including risk-adjustment calculations as well as internal consistency checks for logical inaccuracies. In the FY 2015 IRF PPS proposed rule (79 FR 26342 through 26343), we proposed that beginning with quality data affecting the FY 2016 IRF PPS annual increase factor (CY 2014 data) and beyond, IRF providers must meet or exceed a proposed IRF-PAI quality indicator data completion threshold of 95 percent. We proposed to assess the completeness of submitted data by verifying that, for all IRF-PAI Assessments submitted by any given IRF, at least 95 percent of those IRF-PAI Assessments must have 100 percent of the mandatory quality indicator data items completed where, for the purposes of this proposed rule, "completed" is defined as having provided actual patient data as opposed to a non-informative response, such as a dash (–), that indicates the IRF was unable to provide patient data. The proposed threshold of 95 percent is based on the need for complete records, which allows appropriate analysis of quality measure data for the purposes of updating quality measure specifications as they undergo yearly and triennial measure maintenance reviews with the NQF. Additionally, complete data is needed to understand the validity and reliability of quality data items, including risk-adjustment models. Finally, we want to ensure complete quality data from IRF providers, which will ultimately be reported to the public, allowing our beneficiaries to gain an understanding of provider performance related to these quality metrics, and helping them to make informed health care choices. Our data suggests that the majority of current IRF

providers are in compliance with, or exceeding this proposed threshold already. However, we take comment on circumstances that might prevent IRFs from meeting this level of compliance. All items that we propose to require under the IRF QRP are identified in Chapter 4 of the IRF PAI Training Manual, which is available for download on the CMS Web site at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html?redirect=/IRF-Quality-Reporting/>. We additionally proposed that any IRF that does not meet the proposed requirement that 95 percent of all IRF-PAI assessments submitted contain 100 percent of all required quality indicator data items, will be subject to a reduction of 2 percentage points to the applicable FY IRF PPS annual increase factor beginning with FY 2016. To establish this program threshold, we analyzed IRF-PAI quality indicator data item submissions from January 2013 through September 2013, and we believe that the majority of IRF providers will be able to meet the proposed 95 percent data completion threshold. It is our intent to raise this threshold over the next 2 years, through the notice and comment rulemaking process. We proposed that this threshold will have to be met by IRFs, in addition to the CDC NHSN threshold discussed below, to avoid receiving a 2 percentage point reduction to the applicable FY IRF PPS annual increase factor.

2. IRF QRP Data Completion Threshold for Measures Submitted Using the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN)

The IRF QRP, through the FY 2012 IRF PPS final rule, CY 2013 OPPI/ASC final rule, and FY 2014 IRF PPS final rule, requires that IRFs submit CDC-stewarded quality measure data using the CDC's NHSN, including data for the previously finalized CAUTI and Influenza Vaccination Coverage Among Healthcare Personnel (HCP) quality measures. More specifically, we require that IRFs follow CDC quality measure protocols, which require them to complete all data fields required for both numerator and denominator data within NHSN, including the "no events" field for any month during which no infection events were identified. IRFs are required to submit this data on a monthly basis (except for the HCP measure, which is only required to be reported once per year). However, IRFs have until the associated quarterly deadline (135 calendar days

beyond the end of each CY quarter) by which to report infection data to the CDC for each of the 3 months within any give quarter. For more information on the IRF QRP quarterly deadlines, we refer you to Table 10 in section XI.E of this final rule. In the FY 2015 IRF PPS proposed rule (79 FR 26343), we proposed that, beginning with FY 2016 IRF PPS annual increase factor and beyond, this previously finalized requirement for monthly reporting must be met, in addition to the proposed IRF-PAI quality indicator data item completion threshold discussed above, to avoid a 2 percentage point reduction to the applicable FY IRF PPS annual increase factor. That is, we proposed that IRFs must meet a threshold of 100 percent for measures submitted via the NHSN, achieved by submitting relevant infection or vaccination data for each month of any given CY, in addition to meeting the above proposed data item completion threshold for required quality indicator items on the IRF-PAI. As the IRF QRP expands and IRFs begin reporting measures that were previously finalized, but not yet implemented, or newly proposed and finalized measures, we proposed to apply this same threshold.

a. Application of the 2 Percentage Point Reduction for IRF Providers That Fail To Meet the Above-Proposed Data Completion Thresholds

In the FY 2015 IRF PPS proposed rule (79 FR 26343), we proposed that IRFs must meet two separate data completion thresholds to avoid a 2 percentage point reduction to their applicable FY annual increase factor: A data completion threshold of 95 percent for those mandatory data elements collected using the quality indicator items on the IRF-PAI and submitted through QIES; and a second data completion threshold of 100 percent for quality measure data submitted through the CDC's NHSN. We also proposed that these data completion thresholds must be met in addition to the below proposed data accuracy validation threshold of 75 percent, to avoid a 2 percentage point reduction to their applicable FY annual increase factor. While we proposed that IRFs must meet both the data completion and data accuracy thresholds, IRFs cannot have their applicable annual increase factor reduced twice. That is, should an IRF provider fail to meet either one or both of the proposed thresholds, they will only receive one reduction of 2 percentage points to their applicable FY annual increase factor.

We invited comment on these proposals. Our responses to the public

comments we received on this proposal are discussed below.

Comment: A few commenters supported our proposal of data completeness standards, stating that these standards will facilitate more accurate public reporting in the future.

Response: We thank the commenters for taking the time to express their support of our proposal.

Comment: Several commenters believed we should delay the implementation of our data completion threshold. One commenter stated we should not implement this threshold until FY 2016, at the earliest. Other commenters stated that we should apply the standards no earlier than FY 2017.

Response: We would submit that we proposed to begin applying this data completion threshold, beginning with the FY 2016 annual increase factor for IRFs (based on CY 2014 data), and interpret that the commenter stating that we should not implement this proposal until FY 2016, at the earliest, meant that we should apply this threshold to data collected during CY 2016, at the earliest. We believe that it is important that we begin evaluating the completeness of the quality data submitted to CMS as early as possible, in order to ensure the integrity of the IRF QRP data. This data may not only be used for public reporting, but is also used to inform important updates to quality measures undergoing maintenance at the NQF, that occurs on an annual or triennial basis. Additionally, quality data being submitted via the CDC's NHSN during CY 2014, will be used to calculate a baseline "expected" ratio, as well as a Standard Infection Ratio (SIR). Incomplete quality data, including missing monthly submissions of NHSN data, will result in an incomplete, and therefore potentially misleading, SIR. We believe delaying implementation of the application of these data completion thresholds would be a disservice to Medicare beneficiaries, who will eventually use publically reported data to make better informed health care choices for themselves and their families.

Comment: Several commenters stated that CMS should delay implementation and apply these standards no earlier than FY 2017, and additionally commented that it would be inappropriate and unfair to apply the data completeness standards to data submitted before the standards were proposed, and therefore, known to IRFs. One commenter stated that in the hospital IQR program, changes to data submission standards are proposed in advance of—not during or after—the data collection period. One commenter

stated that it would be impermissibly retroactive to apply data completeness thresholds to IRF data submitted prior to October 1, 2014.

Response: We respectfully disagree with the commenters, and believe that we are within our authority to apply these data completion standards to quality data submitted to CMS prior to the effective date of this final rule. Currently, the compliance standard applicable to each IRF is to timely submit all required quality data to CMS, and IRFs should already be ensuring that the data they submit is complete and accurate. Thus, applying a data completion threshold to data submitted during CY 2014 ensures that IRFs are complying with applicable standards, and that payments made to IRFs are based on complete and accurate data.

Comment: One commenter stated that it would be unfair for CMS to apply the proposed data completion threshold to data collected for the first 6 months using the newly revised IRF-PAI that will go into effect on October 1, 2014, and that CMS should only consider the second 6 months of data submitted using the new IRF-PAI when making compliance determinations. The commenter further stated that CMS has, in the past, used a partial year's data to make compliance determinations, and should do so for the FY 2017 compliance determinations, as IRFs will have a greater chance of submitting inaccurate or incomplete data until they are familiar with the updated IRF-PAI.

Response: We thank the commenter for expressing their concern. However, we respectfully disagree with the commenter. While IRFs will be using a new version of the IRF-PAI beginning October 1, 2014, we do not believe that the expanded quality indicator section used for reporting quality data is so substantially different that IRFs will have difficulty submitting complete and accurate data. The newly expanded quality indicator section of the IRF-PAI includes only 1 additional mandatory item compared to the version that is in use currently. Additionally, the data completion threshold, initially, will only look at the mandatory pressure ulcer items, which remain the same; the new mandatory item is related to the Patient Influenza measure, and will not be considered when applying the data completion threshold for FY 2017 compliance determinations. Any expansion of the application of this data completion threshold to IRF quality data will be addressed through notice-and-comment rulemaking.

Final Decision: Having carefully considered the comments we received on the proposed IRF QRP data

completion threshold, and for the reasons discussed above, we are finalizing the IRF data completion threshold for the FY 2016 adjustments to the IRF PPS annual increase factor and beyond, as proposed.

K. Data Validation Process for the FY 2017 Adjustments to the IRF PPS Annual Increase Factor and Beyond

Historically, we have built consistency and internal validation checks into our data submission specifications to ensure that the basic elements of the IRF-PAI assessment conform to requirements such as proper format and facility information. These internal validation checks are automated and occur during the provider submission process, and help ensure the integrity of the data submitted by providers by rejecting submissions or issuing warnings when provider data contain logical inconsistencies. These edit checks are further outlined in the Inpatient Rehabilitation Facility-Patient Assessment Instrument Data Submission Specifications, which are available for download at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html>.

Validation is intended to provide added assurance of the accuracy of the data that will be reported to the public as required by section 1886(j)(7)(E) of the Act. In the FY 2015 IRF PPS proposed rule (79 FR 26343 through 26344), we proposed, for the FY 2016 adjustments to the IRF PPS annual increase factor and subsequent years, to validate the data submitted for quality purposes. Initially, for FY 2016 this data accuracy validation will apply only to the quality indicator items on the IRF-PAI that inform the measure Percent of Patients or Residents with Pressure Ulcers That Are New or Worsened (NQF #0678), including those mandatory data elements that inform the measure calculation, as well as those that inform internal consistency checks for logical inaccuracies. We proposed that as the IRF QRP expands, and as IRFs begin to submit additional data using the quality indicator section of the IRF-PAI, to include those additional data elements in this validation process. We will inform any such expansion of this validation process prior to its occurrence through our routine channels of communication including, but not limited to the IRF QRP Web site, CMS open door forums, national IRF provider trainings, and the Medicare Learning Network Newsletter.

We proposed to validate the data elements submitted to CMS for Percent

of Residents or Patients with Pressure Ulcers That Are New or Have Worsened (Short-Stay) (NQF #0678) under the IRF QRP by requesting the minimum chart data necessary to confirm a statistically valid random sample of 260 providers. From each of those 260 providers, 5 IRF-PAI assessments submitted through National Assessment Collection Database will be randomly selected. In accordance with § 164.512(d)(1)(iii) of the HIPAA Privacy Rule, we will request from these providers the specified portions of the 5 Medicare patient charts that correspond to the randomly selected assessments, which will need to be copied and submitted via traceable mail to a CMS contractor for validation. We proposed that the specific portions of the 5 beneficiary charts will be identified in the written request, but may include: Admission and discharge assessments, relevant nursing notes following the admission, relevant nursing notes preceding the discharge, physician admission summary and discharge summary, and any Assessment of Pressure Ulcer Form the facility may utilize. We proposed that the CMS contractor would utilize the portions of the patient charts to compare that information with the quality data submitted to CMS. Differences that would affect measure outcomes or measure rates would be identified and reported to CMS. These differences could include, but are not limited to, unreported worsened pressure ulcers.

We proposed that all data that has been submitted to the National Assessment Collection Database under the IRF QRP would be subject to the data validation process. Specifically, we proposed that the contractor will request copies of the randomly selected medical charts from each facility via certified mail (or other traceable methods that require a facility representative to sign for CMS correspondence), and the facility will have 45 days from the date of the request (as documented on the request letter) to submit the requested records to the contractor. If the facility does not comply within 30 days, the contractor will send a second certified letter to the facility, reminding the facility that it must return copies of the requested medical records within 45 calendar days following the date of the initial contractor medical record request. If the facility still does not comply, then the contractor will assign a "zero" score to each measure in each missing record. If, however, the facility does comply, the contractor will review the data submitted by the facility using the IRF-

PAI for the mandatory data elements associated with the Pressure Ulcer measure, until such time that IRFs begin to submit additional quality measures that are collected using the quality indicator section of the IRF-PAI. Initially, this review will consist solely of those mandatory data elements that inform the pressure ulcer measure calculations, as well as those that inform checks for logical inconsistencies. We proposed that as IRFs begin to report additional finalized measures, we intend to propose expanding this validation process to other such measures at that time. The contractor will then calculate the percentage of matching data elements which will constitute a validation score. Because we would not be validating all records, we would need to calculate a confidence interval that incorporates a potential sampling error.

To receive the full FY 2016 IRF annual increase factor, we proposed that IRFs in the random sample must attain at least a 75 percent validation score, based upon our validation process, which will use charts requested from patient assessments submitted for FY 2014. We will calculate a 95 percent confidence interval associated with the observed validation score. If the upper bound of this confidence interval is below the 75 percent cutoff point, we will not consider a hospital's data to be "validated" for payment purposes. For example, for a provider who submits all 5 of their charts, each with 9 elements, the provider's score will be based on 45 possible opportunities to report correctly or incorrectly. If the provider correctly scored on 40 of the 45 elements, then their reliability would be 89 percent (40/45). The upper bound of the confidence interval takes into account sampling error and would be higher than this estimated reliability, in this case 96 percent. This number is greater than or equal to 75 percent. Therefore the provider passes validation. We proposed that providers failing the validation requirements would be subject to a 2 percentage point reduction to their applicable annual increase factor. In addition, all providers validated would receive educational feedback, including specific case details.

1. Application of the 2 Percentage Point Reduction for IRF Providers That Fail To Meet the Above-Proposed Data Accuracy Threshold

In the FY 2015 IRF PPS proposed rule (79 FR 26344), we proposed that IRFs must meet a data accuracy threshold of 75 percent to avoid receiving a 2 percentage point reduction to their

applicable FY annual increase factor. We additionally proposed that this data accuracy threshold of 75 percent must be met in addition to the above data completion thresholds (95 percent for data collected using the quality indicator items on the IRF-PAI and submitted using QIES, and 100 percent for data submitted using the CDC's NHSN), to avoid receiving a 2 percentage point reduction to their applicable FY annual increase factor. While we proposed that IRFs must meet both the proposed data accuracy and data completion thresholds, IRFs cannot have their applicable annual payment update reduced twice. That is, should an IRF provider fail to meet either one or both of the proposed thresholds (data completion and/or data accuracy), they will only receive one reduction of 2 percentage points to their applicable FY annual increase factor.

We invited public comment on these proposals and suggestions to improve the utility of the approach and/or reduce the burden on facilities. Our responses to comments we received on this proposal are discussed below.

Comment: One commenter recommended inclusion of NHSN measures in its proposed validation for FY 2017, beginning with the CAUTI measure. Additionally, they suggested CMS explore a secure method of electronic submission of records for the validation process.

Response: We thank the commenter for taking the time to express these views and suggestions regarding validation and will take them into consideration for future validation proposals. The HIPAA Security Rule and HHS policy require CMS to use secure methods of data transmission. We will consider adoption of electronic transmission of records in future rulemaking as a secure file transfer product becomes available to the IRF QRP.

Comment: Several commenters believed that the proposed data validation process is a fundamental step to ensure the accuracy of the IRF quality reporting data.

Response: We thank the commenters for their support of this process.

Comment: One commenter recommended that CMS not move forward with its proposal to complete data validation for the Pressure Ulcer measure or that CMS should delay implementation until at least FY 2016 and should consider the use of a different measure for validation purposes. Additionally the commenter expressed concern that inconsistencies in the medical record would not be the

sole factor used to demonstrate a failure to comply.

Response: We believe that data validation is necessary to ensure the integrity of the data we use in the IRF QRP. We are finalizing that the data validation process for FY 2016 is for the Pressure Ulcer measure. This process would validate those data elements submitted to the QRP that are found in the medical record. We will not be validating individual inconsistencies in each record. However, if we find that record to be non-compliant, yet a facility believed the documentation submitted for validation matches the data elements submitted for the Pressure Ulcer measure, the facility may seek reconsideration of our initial determination.

Comment: One commenter expressed concern that the threshold compliance of 75 percent agreement was too high for this first attempt to validate the Pressure Ulcer data. They stated that there would be a great deal of variability in the reporting of the pressure ulcer measure and that this should be an opportunity for CMS to educate providers on appropriate documentation and reporting to improve the process. Instead, they offered a 60 percent compliance threshold as more appropriate for this initial round of validation.

Response: We thank the commenter for taking time to express concern about possible variability in the pressure ulcer measure. We note that the 75 percent agreement is the single point estimate of the proportion in agreement; we are proposing that the upper bound of a 95 percent confidence interval be the value that must exceed the 75 percent compliance threshold. We believe this takes into account the inherent variability to be found in the Pressure Ulcer measure data. In addition, the 75 percent proportion agreement is consistent with the other data quality programs currently underway, for example, the Hospital Inpatient Quality Reporting Program, 42 CFR 412.140(d)(2), and the Hospital Outpatient Quality Reporting Program, 42 CFR 419.46(e)(2). We believe it is important, where feasible, to promulgate consistent standards when we deal with the various quality data we are collecting.

Final Decision: Having carefully considered the comments we received on the proposed IRF QRP data validation process and data accuracy threshold, and for the reasons discussed above, we are finalizing the IRF data validation process and data accuracy threshold for the FY 2017 adjustments

to the IRF PPS annual increase factor and beyond, as proposed.

L. Electronic Health Record and Health Information Exchange

We believe that all patients, their families, and their health care providers should have consistent and timely access to their health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the patient's care.²⁹ We are committed to accelerating health information exchange (HIE) through the use of electronic health records (EHRs) and other types of health information technology (HIT) across the broader care continuum through a number of initiatives, including: (1) Alignment of incentives and payment adjustments to encourage provider adoption and optimization of HIT and HIE services through Medicare and Medicaid payment policies; (2) adoption of common standards and certification requirements for interoperable HIT; (3) support for privacy and security of patient information across all HIE-focused initiatives; and (4) governance of health information networks. These initiatives are designed to improve care delivery and coordination across the entire care continuum and encourage HIE among all health care providers, including professionals and hospitals eligible for the Medicare and Medicaid EHR Incentive Programs and those who are not eligible for the EHR Incentive Programs. The Office of the National Coordinator for Health Information Technology (ONC) is currently exploring regulatory ways to expand the ONC HIT Certificate Program to more easily accommodate HIT certification for technology used in other types of health care settings where individual or institutional health care providers are not typically eligible for incentive payments under the EHR Incentive Programs, such as long-term and post-acute care and behavioral health settings. ONC has previously provided guidance for EHR technology developers serving providers ineligible for incentives under the EHR Incentive Programs titled "Certification Guidance for EHR Technology Developers Serving Health Care Providers Ineligible for Medicare and Medicaid EHR Incentive Payments."³⁰

We believe that HIE and the use of certified EHR technology by IRFs (and other providers ineligible for the

Medicare and Medicaid EHR Incentive Programs) can effectively and efficiently help providers improve internal care delivery practices, support management of patient care across the continuum, and enable the reporting of electronically specified clinical quality measures (eCQMs). More information on the identification of EHR certification criteria and development of standards applicable to IRFs can be found at:

- <http://healthit.gov/policy-researchers-implementers/standards-and-certification-regulations>
- <http://www.healthit.gov/facac/FACAS/health-it-policy-committee/htpc-workgroups/certificationadoption>
- <http://wiki.siframework.org/LCC+LTPAC+Care+Transition+SWG>
- <http://wiki.siframework.org/Longitudinal+Coordination+of+Care>

In the FY 2015 IRF PPS proposed rule (79 FR 26344 through 26345), we solicited feedback on the feasibility and desirability of electronic health record adoption and use of HIE in IRFs. We also solicited public comment on the need to develop electronic clinical quality measures, and the benefits and limitations of implementing these measures for IRF providers. Our responses to the comments we received on this topic are discussed below.

Comment: We received several comments in response to its solicitation for input related to EHR adoption and usage and HIE among IRFs. A commenter suggested that we consider a structural measure similar to the Inpatient Psychiatric Facility Quality Reporting Program to gain insight on the feasibility of EHR adoption and use of HIE in IRFs. Some commenters conveyed concerns related to current EHR/HIE adoption in IRFs, including burden associated with EHR use and time and burden associated with the implementation of the technical infrastructure needed to accommodate EHRs. Many commenters noted the lack of EHR incentive funding and integration of IRFs in activities such as those related to the design of the HIE exchanges, electronic health record interoperability standards, electronic health record incentive payment programs, electronic quality measurement development, as well as the Medicare EHR Incentive Programs, and therefore conveyed concerns about the feasibility and appropriateness of requiring electronic clinical quality measure use at this time in the absence of incentive funding for IRFs. Some commenters suggested collaboration with CMS and the IRF community to expand the reach of HIEs and the

interoperability standards to include IRFs. Some commenters also requested that CMS extend incentive payments to IRFs, allowing HIEs to include IRFs in the development of clinically appropriate electronic quality measures for IRFs. A commenter recommended that CMS not apply the requirement of electronic clinical quality measures reporting at this time, and another commenter requested that CMS allow time for the process of data collection using electronic measures to mature before requiring them.

Response: We thank the commenters for their recommendations and concerns. We believe that these recommendations, including interoperability standards which we interpret to mean those that would align with what has been adopted by the Secretary, and concerns are important considerations related to EHR adoption and HIE usage in the IRF setting. We thank the commenter for their suggestion for us to consider the implementation of a structural measure similar to the Inpatient Psychiatric Facility Report Program in the IRF QRP to gain insight on the feasibility of EHR adoption and use of HIE in IRFs, and we will take this suggestion under consideration.

M. Method for Applying the Reduction to the FY 2015 IRF Increase Factor for IRFs That Fail To Meet the Quality Reporting Requirements

As previously noted, section 1886(j)(7)(A)(i) of the Act requires the application of a 2-percentage point reduction of the applicable market basket increase factor for IRFs that fail to comply with the quality data submission requirements. In compliance with 1886(j)(7)(A)(i) of the Act, we will apply a 2-percentage point reduction to the applicable FY 2015 market basket increase factor (2.2 percent) in calculating an adjusted FY 2015 standard payment conversion factor to apply to payments for only those IRFs that failed to comply with the data submission requirements. As previously noted, application of the 2-percentage point reduction may result in an update that is less than 0.0 for a fiscal year and in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Also, reporting-based reductions to the market basket increase factor will not be cumulative; they will only apply for the FY involved. Table 12 shows the calculation of the adjusted FY 2015 standard payment conversion factor that will be used to compute IRF PPS payment rates for any IRF that failed to meet the quality reporting requirements

²⁹ The Department of Health & Human Services August 2013 Statement, "Principles and Strategies for Accelerating Health Information Exchange."

³⁰ http://www.healthit.gov/sites/default/files/generalcertexchange_guidance_final_9-9-13.pdf.

for the period from January 1, 2013, through December 31, 2013.

TABLE 12—CALCULATIONS TO DETERMINE THE ADJUSTED FY 2015 STANDARD PAYMENT CONVERSION FACTOR FOR IRFs THAT FAILED TO MEET THE QUALITY REPORTING REQUIREMENT

Explanation for adjustment	Calculations
Standard Payment Conversion Factor for FY 2014	\$14,846
Market Basket Increase Factor for FY 2015 (2.9 percent), reduced by 0.5 percentage point reduction for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, reduced by 0.2 percentage point in accordance with sections 1886(j)(3)(C) and (D) of the Act and further reduced by 2 percentage points for IRFs that failed to meet the quality reporting requirement	× 1.0020
Budget Neutrality Factor for the Wage Index and Labor-Related Share	× 1.0017
Budget Neutrality Factor for the Revisions to the CMG Relative Weights	× 1.0000
Final Adjusted FY 2015 Standard Payment Conversion Factor	= \$14,901

We did not receive any comments on the proposed method for applying the reduction to the FY 2015 IRF increase factor for IRFs that fail to meet the quality reporting requirements.

Final Decision: As we did not receive any comments on the proposed method for applying the reduction to the FY 2015 IRF increase factor for IRFs that fail to meet the quality reporting requirements, we are finalizing the proposed methodology.

XIII. Miscellaneous Comments

Comment: Several commenters suggested that we consider imposing a cap on the amount of outlier payments an individual IRF can receive under the IRF PPS.

Response: As we did not propose any limits on the amount of outlier payments an individual IRF can receive, this comment is outside the scope of the proposed rule. However, any future consideration given to imposing a limit on outlier payments would have to carefully analyze and take into consideration the effect on access to IRF care for certain high-cost patient populations.

Comment: Several commenters requested that we allow IRFs access to the presumptive compliance reports that the MACs use to determine whether or not an IRF has met the 60 percent rule requirements under the presumptive methodology. These same commenters also requested that we provide IRFs with patient-level detail regarding which patients were counted as presumptively meeting the 60 percent rule requirements and which patients were not counted as meeting the requirements. Other commenters requested that we ensure that all MACs allow for a review process prior to an IRF declassification for the IRF to dispute a 60 percent rule determination.

Response: As we did not propose any changes to these operational aspects of the 60 percent rule enforcement, these

comments are outside the scope of the proposed rule. However, we will take these suggestions into consideration for future operational enhancements.

Comment: Several commenters requested that we release the exact software specifications and algorithms for enforcement of the 60 percent rule policies. Other commenters expressed concerns that we are fundamentally altering the technical code specifications that are used in determining an IRF's presumptive compliance with the 60 percent rule. Additionally, some commenters indicated that there is an inconsistency with the software specifications because they mark a record as failing the presumptive methodology test if the case has an IGC and one of the excluded Etiologic Diagnoses, even if the case has a comorbidity that would qualify the case as counting for the presumptive methodology.

Response: As we did not propose changes to the technical specifications, these comments are outside the scope of the proposed rule. The technical specifications for the presumptive methodology determination are available for download from the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Criteria.html>. As we are continually looking to improve the technical specifications and the accuracy with which we evaluate providers' compliance with the 60 percent rule requirements, we will take these commenters' suggestions and concerns into consideration for future updates to the technical specifications.

Comment: Several commenters suggested that we re-examine the conditions that are included on the list of tier comorbidities (otherwise known in this final rule as the "List of Comorbidities") using the most recent 3 years of data, and revise this list for FY

2016. In addition, one commenter suggested that we allow for multiple tier payments if a patient has multiple comorbidities that qualify for tier payments, instead of only recognizing the one comorbidity that qualifies for the highest payment.

Response: As we did not propose any changes to the methodology or policy regarding the determination of the tier comorbidities, these comments are outside the scope of the proposed rule. We appreciate the commenters' suggestions, and will consider these suggestions for future analyses.

Comment: One commenter suggested that we continue to explore ways to ensure comparability of payments across Medicare's post-acute care settings.

Response: We appreciate the commenter's suggestion. Although the comment is beyond the scope of this rule and reaches beyond the IRF PPS, we appreciate the forward thinking nature of this comment and will try to consider ways in which this suggestion may be considered for future analysis.

Comment: Several commenters expressed concern about the proposal that was included in the most recent President's Budget Proposal to increase the compliance threshold for the 60 percent rule to 75 percent.

Response: Since the Secretary does not have the authority to make this change, this comment is outside the scope of the proposed rule.

XIV. Provisions of the Final Regulations

In this final rule, we are adopting the provisions set forth in the FY 2015 IRF proposed rule (79 FR 26308), except as noted elsewhere in the preamble. Specifically:

- We will update the FY 2015 IRF PPS relative weights and average length of stay values using the most current and complete Medicare claims and cost report data in a budget-neutral manner,

as discussed in section IV of this final rule.

- We will freeze the IRF facility-level adjustment factors at FY 2014 levels, as discussed in section V of this final rule.

- We will update the FY 2015 IRF PPS payment rates by the market basket increase factor, based upon the most current data available, with a 0.2 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act and a productivity adjustment required by section 1886(j)(3)(C)(ii)(I) of the Act, as described in section VI of this final rule.

- We will indicate the Secretary's Final Recommendation for updating IRF PPS payments for FY 2015, in accordance with the statutory requirements, as described in section VI of this final rule.

- We will update the FY 2015 IRF PPS payment rates by the FY 2015 wage index and the labor-related share in a budget-neutral manner, as discussed in section VI of this final rule.

- We will calculate the final IRF Standard Payment Conversion Factor for FY 2015, as discussed in section VI of this final rule.

- We will update the outlier threshold amount for FY 2015, as discussed in section VII of this final rule.

- We will update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2015, as discussed in section VII of this final rule.

- We will adopt revisions to the list of eligible diagnosis codes that are used to determine presumptive compliance under the 60 percent rule in section VIII of this final rule.

- We will adopt revisions to the list of eligible impairment group codes that presumptively meet the 60 percent rule compliance criteria in section VIII of this final rule.

- We will collect data on the amount and mode (that is, of Individual, Concurrent, Group, and Co-Treatment) of therapies provided in IRFs according to occupational, speech, and physical therapy disciplines via the IRF-PAI in section IX of this final rule.

- We will adopt a revision to the IRF-PAI to indicate whether the case meets the regulatory requirements for arthritis cases in section X of this final rule.

- We will adopt the conversion of the IRF PPS to ICD-10-CM, effective when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions, in section XI of this final rule.

- We will adopt revisions and updates to quality measures and reporting requirements under the

quality reporting program for IRFs in accordance with section 1886(j)(7) of the Act, as discussed in section XII of this final rule.

XV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30 days' notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

This final rule does not impose any new information collection requirements as outlined in the regulation text. However, this final rule does make reference to associated information collections that are not discussed in the regulation text contained in this document. The following is a discussion of these information collections, some of which have already received OMB approval.

A. ICRs Regarding the IRF QRP

Updates to IRF QRP

As stated in section XI of this final rule, we have finalized 2 new measures for use in the IRF QRP that will affect the increase factor for FY 2017. These quality measures are: National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) and National Healthcare Safety Network (NHSN) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717). We proposed that these measures would be collected via the CDC's NHSN data submission system (<http://www.cdc.gov/nhsn/>). The NHSN is a secure, Internet-based healthcare-associated infection tracking system that is maintained and managed by the CDC.

There are currently approximately 1,140 IRFs in the United States paid

under the IRF PPS that are already required to submit CAUTI data to the CDC's NHSN. We believe that any burden increase related to complying with the IRF QRP requirements for submission of the MRSA and CDI measures will be minimal for those IRFs that are already familiar with the NHSN submission process, for several reasons. First, these IRFs have already completed the initial setup and have become familiar with reporting data in the NHSN system due to the requirement to report the CAUTI measure. Second, due to their participation in a wide range of mandatory reporting and quality improvement programs, there are at least 15 states that require IRFs to report MRSA bacteremia data and CDI data to the NHSN. The most significant burden associated with these quality measures is the time and effort associated with collecting and submitting the data on the MRSA and CDI measures for IRFs that are not currently reporting any measures beyond the current CAUTI data requirement into the CDC's NHSN system.

Based on submissions to the NHSN, we now estimate that each IRF will execute approximately 5 NHSN submissions per month: 1 MRSA bacteremia event, 1 *C. difficile* event and 3 CAUTI events (60 events per IRF annually). This equates to a total of approximately 68,400 submissions of events to the NHSN from all IRFs per year. The CDC estimated the public reporting burden of the collection of information for each measure to include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. MRSA and *C. difficile* are estimated to be an average of 15 minutes per response (10 minutes of clinical (registered nurse) time, and 5 minutes of clerical (Medical Records or Health Information Technician); CAUTI is estimated to be an average of 29 minutes per response. Each IRF must also complete a Patient Safety Monthly Reporting Plan estimated at 35 minutes and a Denominator for Specialty Care Area, which is estimated at 5 hours per month. Based on this estimate, we expect each IRF would expend 7.53 hours per month reporting to the NHSN. Additionally, each IRF must submit the Healthcare Personnel Vaccination measure, which the CDC estimates will take 10 minutes of clerical time. Based on this estimate, we expect each IRF would expend 78.97 clinical hours per year reporting to the NHSN, or 90,026 hours for all IRFs. According to the U.S.

Bureau of Labor and Statistics, the mean hourly wage for a registered nurse (RN) is \$33.13; the mean hourly wage for a medical records and health information technician is \$16.81. However, to account for overhead and fringe benefits, we have doubled the mean hourly wage, making it \$66.26 for an RN and \$33.62 for a Medical Record or Health Information Technician. We estimate that the annual cost per each IRF would be \$5,162.09 and that the total yearly cost to all IRFs for the submission of data to NHSN would be \$5,882,782.60. While the quality measures previously discussed are subject to the PRA, we believe that the associated burden is approved under OMB control number 0920-0666, with an expiration date of November, 31, 2016.

In the FY 2014 IRF PPS rule (78 FR 47923 through 47925), we provided burden estimates for measures adopted in that rule. Updated Collection of Information Requirements for each of those measures is described below:

a. All-Cause Unplanned Readmission Measure for 30 Days Post Discharge From Inpatient Rehabilitation Facilities

As stated in the FY 2014 IRF PPS rule (78 FR 47923 through 47925), data for this measure will be derived from Medicare claims, and therefore, will not add any additional reporting burden for IRFs.

b. Percent of Residents or Patients With Pressure Ulcers That Are New or Have Worsened (Short-Stay) (NQF #0678)

In the FY 2015 IRF PPS proposed rule (79 FR 26346), we stated that we expect that the admission and discharge pressure ulcer data will be collected by a clinician such as an RN because the assessment and staging of pressure ulcers requires a high degree of clinical judgment and experience. We estimated that it will take approximately 10 minutes of time by the RN to perform the admission pressure ulcer assessment. We further estimated that it will take an additional 15 minutes of time to complete the discharge pressure ulcer assessment.

We estimated that there are 359,000 IRF-PAI submissions per year³ and that there are 1,140 IRFs in the U.S. reporting quality data to CMS. Based on these figures, we estimated that each IRF will submit approximately 315 IRF-PAIs per year. Assuming that each IRF-PAI submission requires 25 minutes of time by an RN at an average hourly wage of \$66.26 (including fringe benefits and overhead), to complete the "Quality Indicator" section, the yearly cost to each IRF would be \$8,696.63 and

the annualized cost across all IRFs would be \$9,914,158.20.

In the FY 2015 IRF PPS proposed rule (79 FR 26346), we also stated we expected that most IRFs will use administrative personnel, such as a medical secretary or medical data entry clerk, to perform the task of entering the IRF-PAI pressure ulcer Assessment data. We estimated that this data entry task will take no more than 3 minutes for the "Quality Indicator" section of each IRF-PAI record or 15.75 hours for each IRF annually. The average hourly wage for a Medical Records & Health Information Technician is \$33.62 (including fringe benefits and overhead). Again, as we noted above, there are approximately 359,000 IRF-PAI submissions per year and 1,140 IRFs reporting quality data to CMS. Given this wage information, the estimated total annual cost across all reporting IRFs for the time required for entry of pressure ulcer data into the IRF-PAI by a medical record or health information technician (including fringe benefits and overhead) is \$603,652.80. We further estimated the average yearly cost to each individual IRF to be \$529.52.

We estimated that the combined annualized time burden related to the pressure ulcer data item set for work performed, by the both clinical and administrative staff, will be 147 hours for each individual IRF and 167,580 hours across all IRFs. The total estimated annualized cost for collection and submission of pressure ulcer data is \$9,226.15 for each IRF and \$10,517,811 across all IRFs. We estimated the cost for each pressure ulcer submission to be \$29.29.

c. Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)

IRFs are already required to complete and transmit certain IRF-PAI data on all Medicare Part A Fee-for-Service and Medicare Part C (Medicare Advantage) patients to receive payment from Medicare. In the FY 2015 IRF PPS proposed rule (79 FR 26347), we estimated that completion of the Patient Influenza measure data items will take approximately 5 minutes to complete. The Patient Influenza item set consists of three data items (for example, questions). Each item is straightforward and does not require physical assessment of the patient for completion. We estimated that it will take approximately 0.7 minutes to complete each item, or 2.1 minutes to complete all items related to the Patient Influenza measure. However, in some

cases, the person completing this item set may need to consult the patient's medical record to obtain data about the patient's influenza vaccination.

Therefore, we have allotted an additional 1.66 minutes per item, for a total of 7.1 minutes to complete the Patient Influenza measure data items.

In the FY 2015 IRF PPS proposed rule (79 FR 26347), we noted that there are approximately 359,000 IRF-PAIs completed annually across all 1,140 IRFs that report IRF quality data to CMS. This breaks down to approximately 315 IRF-PAIs completed by each IRF yearly. We additionally estimated that the annual time burden for reporting the Patient Influenza measure data is 42,481 hours across all IRFs in the U.S. and 37.26 hours for each individual IRF. Again, we have estimated the mean hourly wage for an RN (including fringe benefits and overhead) to be \$66.26. Taking all of the above information into consideration, we estimate the annual cost across all IRFs for the submission of the Patient Influenza measure data to be \$2,814,791.06. We further estimated the cost for each individual IRF to be \$2,469.11.

Lastly, in the FY 2015 IRF PPS proposed rule (79 FR 26347), we proposed to validate data submitted to CMS by requesting portions of patient's charts be copied and mailed to a CMS validation contractor. We estimated the size of each section we proposed to request as follows: We stated that we anticipate that the first 3 days of nurses notes will be approximately 15 pages; the last 3 days of nurses notes will be approximately 10 pages; the physician or physician's assistant's admission history and physical will be approximately 30 pages; the physician or physician's assistant's discharge summary will be approximately 15 pages; nurses admission database is approximately 40 pages; pressure ulcer assessment assessments will be approximately 30 pages; physicians progress notes will be approximately 30 pages; physicians orders will be approximately 30 pages and lab reports to be approximately 70 pages. We estimated the total submission to be approximately 270 pages in length. The FY 2013 IPPS/LTCH PPS final rule (77 FR 53745) estimates the appropriate cost for chart submission to be 12 cents per page and \$4.00 shipping. Two hundred seventy pages at a rate of \$0.12 per page with a \$4.00 shipping cost would be \$36.40 per chart. We proposed that 260 providers will be randomly selected for validation, and we proposed to request 5 charts from each selected provider for a total cost of \$47,320 for all IRF

providers, or \$182.00 for any randomly selected IRF provider.

We did not receive any public comments on the above IRF QRP Information Collection Request section of the FY 2015 IRF PPS proposed rule. Additionally, in section XI of this final rule, we have finalized the adoption of the following two measures: NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); and NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717). We further confirmed that the previously finalized measures discussed in section XII.B. will continue to be required for the IRF QRP.

B. ICRs Regarding Individual, Concurrent, Group, and Co-Treatment Therapy Data on the IRF-PAI

As stated in section IX. of this final rule, we are including a new Therapy Information Section in the IRF-PAI that will require IRF providers to submit data regarding the amount and mode (that is, Individual, Concurrent, Group, and Co-Treatment) of therapy that patients are receiving and in which therapy discipline (PT, OT, speech/language) beginning on October 1, 2015.

Under Medicare's conditions of participation for hospitals that provide rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services at § 482.56, the provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice and must also meet the requirements at § 409.17, according to which IRFs are required to furnish physical therapy, occupational therapy or speech-language pathology services under a plan that, among other things, "[p]rescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual." (Such services may also be furnished under plan requirements specific to the payment policy under which the services are rendered, if applicable.) In addition, the IRF coverage requirements at § 412.622(a)(3)(ii), (4), require the IRF to document that the patient "[g]enerally requires and can reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program." As Medicare already requires extensive documentation of the type, amount, frequency, and duration of physical therapy, occupational therapy, or speech-language pathology services

furnished to individuals in the IRF setting, we do not believe that IRFs will incur any additional burden related to the collection of the data for the proposed new Therapy Information Section. In accordance with 5 CFR 1320.3(b)(2), we believe the burden associated with this requirement is exempt from the PRA as it is a usual and customary business practice. The time, effort, and financial resources necessary to comply with this requirement would be incurred in the course of each IRF conducting its normal business activities.

We anticipate that it will take approximately 4 minutes to retrieve the therapy data from the patient's medical record and transfer the required data to the IRF-PAI for submission. We believe this task can be completed by any clinician in the IRF. To calculate the burden, we obtained hourly wage rates for social worker assistants, licensed practical nurses (LPN), recreational therapists, social workers, dietitians and nutritionists, RN, speech language pathologists, audiologists, occupational therapists, and physical therapists, all of whom may complete the IRF-PAI, from the Bureau of Labor Statistics (<http://www.bls.gov/ooh/healthcare/home.htm>). The \$26.52 rate is a blend of all of these categories, and reflects the fact that IRF providers have historically used all of these clinicians for preparation and coding of the IRF-PAI. However, to account for overhead and fringe benefits, we double the average rate, making it \$53.04. On average, an IRF submits approximately 300 IRF-PAIs annually and when multiplied by 4 minutes to complete the proposed new Therapy Information Section, the total estimated annual hour burden per each IRF is 20 hours. We estimate the total cost burden to each IRF for reporting the proposed therapy data will be \$1,060 annually. Since there are a total of 1,140 IRFs, we estimate the total burden cost across all IRFs for submitting therapy data is \$1.2 million.

We received 40 comments on the information collection requirements regarding the Individual, Concurrent, Group, and Co-Treatment Therapy data on the IRF-PAI, which are summarized below.

Comment: Many commenters suggested that the therapy collection item would be excessively burdensome and should be removed. The commenters suggested that CMS has underestimated the cost and time it would take providers to implement this proposed policy, implying that additional IRF staff would need to be employed to fulfill the data collection requirement. A few commenters even

suggested that the therapy data CMS is proposing to collect is redundant since the data could be found on IRF patient claims. Additionally, commenters suggested that the proposed therapy data collection requirement does not seem to provide any value to the patient and would ultimately divert clinical resources from patient care to administrative functions compromising patients' health outcomes instead of increasing quality of care. Ultimately, the commenters urged CMS to focus on the outcomes of rehabilitative care rather than regulatory mandates.

Response: We recognize and have taken into account that the addition of the therapy collection item will increase the time it takes for providers to complete the IRF-PAI. However, IRF clinicians are currently required to thoroughly document all treatment information in the patients' medical record. We believe that in order to fulfill this requirement, IRFs are already required to document in detail the amount and mode of therapy that a patient receives. We do not believe that it would take an excessive amount of additional time and/or training to transfer that information from the medical record to the IRF-PAI. We certainly do not believe that IRFs would need to employ additional staff to meet this data collection requirement. The additional cost that a facility would incur in making updates to its electronic systems is considered the cost of doing business, and that is not something that we believe should be taken into account when preparing our burden estimates.

In response to the commenters' suggestions to minimize the burden associated with the therapy data collection, we are choosing not to adopt the proposed requirement to record the average number of minutes by mode and type of therapy for weeks 3 and beyond of a patient's IRF stay. Instead, we will require IRFs to report only the total number of minutes of therapy provided to a patient, by mode and type of therapy, for week 1 and week 2 of the IRF stay. Additionally, we are adding Concurrent Therapy and revising the Group Therapy definition so that both types of therapy are clearly differentiated. Providers indicated that this change would be helpful to reduce burden, as this is more consistent with the way they currently keep their records. We believe that these changes will substantially lower the amount of burden associated with this data collection.

We respectfully disagree with the commenters' assertion that this information is included on the IRF claim. The therapy data on the IRF

claim is not reported in a consistent manner, and we do not believe that it would be as beneficial as the proposed data collection when developing future policy regarding IRF therapy. We believe it is important to collect the most accurate and reliable information in order to develop future policy to increase the quality of care for IRF patients. Ultimately, we believe that by requiring providers to report each patient's therapy information, in an effort to develop future policies and procedures regarding the amount and mode of therapy given, we are in fact focusing on improving the outcomes of the intensive rehabilitation that patients receive.

We will be submitting a revision of the IRF-PAI information collection request currently approved under OMB control number 0938-0842.

If you comment on these information collection and recordkeeping requirements, please submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS-1608-F], Fax: (202) 395-6974; or Email: OIRA_submission@omb.eop.gov.

XVI. Regulatory Impact Analysis

A. Statement of Need

This final rule updates the IRF prospective payment rates for FY 2015 as required under section 1886(j)(3)(C) of the Act. It responds to section 1886(j)(5) of the Act, which requires the Secretary to publish in the **Federal Register** on or before the August 1 that precedes the start of each fiscal year, the classification and weighting factors for the IRF PPS's case-mix groups and a description of the methodology and data used in computing the prospective payment rates for that fiscal year.

This rule implements sections 1886(j)(3)(C) and (D) of the Act. Section 1886(j)(3)(C)(ii)(I) of the Act requires the Secretary to apply a multi-factor productivity adjustment to the market basket increase factor, and to apply other adjustments as defined by the Act. The productivity adjustment applies to FYs from 2012 forward. The other adjustments apply to FYs 2010 through 2019.

This rule also adopts some policy changes within the statutory discretion afforded to the Secretary under section 1886(j) of the Act. We will collect data on the amount and mode (that is, Individual, Concurrent, Group, and Co-Treatment) of therapy provided in the IRF setting according to therapy discipline, revise the list of impairment group codes that presumptively meet

the 60 percent rule compliance criteria, provide a way for IRFs to indicate on the IRF-PAI form whether the prior treatment and severity requirements have been met for arthritis cases to presumptively meet the 60 percent rule compliance criteria, and revise and update quality measures and reporting requirements under the IRF quality reporting program. In this final rule, we also address the implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) for the IRF prospective payment system (PPS), effective when ICD-10-CM becomes the required medical data code set for use on Medicare claims and IRF-PAI submissions.

B. Overall Impacts

We have examined the impacts of this final rule as required by Executive Order 12866 (September 30, 1993, Regulatory Planning and Review), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96-354) (RFA), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for a major final rule with economically significant effects (\$100 million or more in any 1 year). We estimate the total impact of the policy updates described in this final rule by comparing the estimated payments in FY 2015 with those in FY 2014. This analysis results in an estimated \$180 million increase for FY 2015 IRF PPS payments. As a result, this final rule is designated as economically "significant" under section 3(f)(1) of Executive Order 12866, and hence a major rule under the Congressional Review Act. Also, the rule has been reviewed by OMB.

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for

regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most IRFs and most other providers and suppliers are small entities, either by having revenues of \$7 million to \$35.5 million or less in any 1 year depending on industry classification, or by being nonprofit organizations that are not dominant in their markets. (For details, see the Small Business Administration's final rule that set forth size standards for health care industries, at 65 FR 69432 at http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf, effective March 26, 2012.) Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IRFs or the proportion of IRFs' revenue that is derived from Medicare payments. Therefore, we assume that all IRFs (an approximate total of 1,100 IRFs, of which approximately 60 percent are nonprofit facilities) are considered small entities and that Medicare payment constitutes the majority of their revenues. The Department of Health and Human Services generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. As shown in Table 13, we estimate that the net revenue impact of this final rule on all IRFs is to increase estimated payments by approximately 2.4 percent. However, we find that certain categories of IRF providers would be expected to experience revenue impacts in the 3 percent range. We estimate a 3.1 percent overall impact for 141 urban IRFs and 15 rural IRFs in the Middle Atlantic region, a 3.2 increase for 101 urban IRFs in the Pacific region, a 3.3 increase for 27 rural IRFs in the West North Central region, and a 4.4 increase for four rural IRFs in the Pacific region. As a result, we anticipate this final rule will have a net positive impact on a substantial number of small entities. Medicare Administrative Contractors are not considered to be small entities. Individuals and states are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has

fewer than 100 beds. As discussed in detail below, the rates and policies set forth in this final rule will not have a significant impact (not greater than 3 percent) on rural hospitals based on the data of the 165 rural units and 17 rural hospitals in our database of 1,142 IRFs for which data were available.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–04, enacted on March 22, 1995) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold level is approximately \$141 million. This final rule will not impose spending costs on state, local, or tribal governments, in the aggregate, or by the private sector, of greater than \$141 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. As stated above, this final rule will not have a substantial effect on state and local governments, preempt state law, or otherwise have a federalism implication.

C. Detailed Economic Analysis

1. Basis and Methodology of Estimates

This final rule sets forth policy changes and updates to the IRF PPS rates contained in the FY 2014 IRF PPS final rule (78 FR 47860). Specifically, this final rule updates the CMG relative weights and average length of stay values, the wage index, and the outlier threshold for high-cost cases. This final rule also applies a MFP adjustment to the FY 2015 RPL market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.2 percentage point reduction to the FY 2015 RPL market basket increase factor in accordance with sections 1886(j)(3)(C)(ii)(II) and –(D)(iv) of the Act. Further, this final rule contains additional changes to the presumptive methodology and additional therapy and quality data collection that are expected to result in some additional financial effects on IRFs. In addition, section XII of this rule discusses the implementation of the required 2 percentage point reduction of the market basket increase factor for any IRF that fails to meet the IRF quality reporting requirements, in accordance with section 1886(j)(7) of the Act.

We estimate that the impact of the changes and updates described in this final rule will be a net estimated increase of \$180 million in payments to IRF providers. This estimate does not include the estimated impacts of the additional changes to the presumptive compliance method and the additional therapy and quality data collection, as discussed in section 8 of this Economic Analysis. In addition, it does not include the implementation of the required 2 percentage point reduction of the market basket increase factor for any IRF that fails to meet the IRF quality reporting requirements (as discussed in section 9 of this Economic Analysis). The impact analysis in Table 13 of this final rule represents the projected effects of the updates to IRF PPS payments for FY 2015 compared with the estimated IRF PPS payments in FY 2014. We determine the effects by estimating payments while holding all other payment variables constant. We use the best data available, but we do not attempt to predict behavioral responses to these changes, and we do not make adjustments for future changes in such variables as number of discharges or case-mix.

We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to forecasting errors because of other changes in the forecasted impact time period. Some examples could be legislative changes made by the Congress to the Medicare program that would impact program funding, or changes specifically related to IRFs. Although some of these changes may not necessarily be specific to the IRF PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon IRFs.

In updating the rates for FY 2015, we are adopting standard annual revisions described in this final rule (for example, the update to the wage and market basket indexes used to adjust the federal rates). We are also implementing a productivity adjustment to the FY 2015 RPL market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.2 percentage point reduction to the FY 2015 RPL market basket increase factor in accordance with sections 1886(j)(3)(C)(ii)(II) and –(D)(iv) of the Act. We estimate the total increase in payments to IRFs in FY 2015, relative to FY 2014, will be approximately \$180 million.

This estimate is derived from the application of the FY 2015 RPL market basket increase factor, as reduced by a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.2 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and –(D)(iv) of the Act, which yields an estimated increase in aggregate payments to IRFs of \$165 million. Furthermore, there is an additional estimated \$15 million increase in aggregate payments to IRFs due to the update to the outlier threshold amount. Outlier payments are estimated to increase from approximately 2.8 percent in FY 2014 to 3.0 percent in FY 2015. Therefore, summed together, we estimate that these updates will result in a net increase in estimated payments of \$180 million from FY 2014 to FY 2015.

The effects of the updates that impact IRF PPS payment rates are shown in Table 13. The following updates that affect the IRF PPS payment rates are discussed separately below:

- The effects of the update to the outlier threshold amount, from approximately 2.8 percent to 3.0 percent of total estimated payments for FY 2015, consistent with section 1886(j)(4) of the Act.
- The effects of the annual market basket update (using the RPL market basket) to IRF PPS payment rates, as required by section 1886(j)(3)(A)(i) and sections 1886(j)(3)(C) and –(D) of the Act, including a productivity adjustment in accordance with section 1886(j)(3)(C)(i)(I) of the Act, and a 0.2 percentage point reduction in accordance with sections 1886(j)(3)(C) and –(D) of the Act.
- The effects of applying the budget-neutral labor-related share and wage index adjustment, as required under section 1886(j)(6) of the Act.
- The effects of the budget-neutral changes to the CMG relative weights and average length of stay values, under the authority of section 1886(j)(2)(C)(i) of the Act.
- The total change in estimated payments based on the FY 2015 payment changes relative to the estimated FY 2014 payments.

2. Description of Table 13

Table 13 categorizes IRFs by geographic location, including urban or rural location, and location for CMS's 9 census divisions (as defined on the cost report) of the country. In addition, the table divides IRFs into those that are separate rehabilitation hospitals (otherwise called freestanding hospitals in this section), those that are rehabilitation units of a hospital

(otherwise called hospital units in this section), rural or urban facilities, ownership (otherwise called for-profit, non-profit, and government), by teaching status, and by disproportionate share patient percentage (DSH PP). The top row of Table 13 shows the overall impact on the 1,142 IRFs included in the analysis.

The next 12 rows of Table 13 contain IRFs categorized according to their geographic location, designation as either a freestanding hospital or a unit of a hospital, and by type of ownership; all urban, which is further divided into urban units of a hospital, urban freestanding hospitals, and by type of ownership; and all rural, which is further divided into rural units of a hospital, rural freestanding hospitals, and by type of ownership. There are 960 IRFs located in urban areas included in our analysis. Among these, there are 732 IRF units of hospitals located in urban areas and 228 freestanding IRF hospitals located in urban areas. There are 182 IRFs located in rural areas included in our analysis. Among these, there are 165 IRF units of hospitals located in rural areas and 17 freestanding IRF hospitals located in rural areas. There are 339 for-profit IRFs. Among these, there are 335 IRFs in urban areas and 64 IRFs in rural areas. There are 673 non-profit IRFs. Among these, there are 567 urban IRFs and 106 rural IRFs. There are 70 government-owned IRFs. Among these, there are 58 urban IRFs and 12 rural IRFs.

The remaining four parts of Table 13 show IRFs grouped by their geographic location within a region, by teaching status, and by DSH PP. First, IRFs located in urban areas are categorized for their location within a particular one

of the nine Census geographic regions. Second, IRFs located in rural areas are categorized for their location within a particular one of the nine Census geographic regions. In some cases, especially for rural IRFs located in the New England, Mountain, and Pacific regions, the number of IRFs represented is small. IRFs are then grouped by teaching status, including non-teaching IRFs, IRFs with an intern and resident to average daily census (ADC) ratio less than 10 percent, IRFs with an intern and resident to ADC ratio greater than or equal to 10 percent and less than or equal to 19 percent, and IRFs with an intern and resident to ADC ratio greater than 19 percent. Finally, IRFs are grouped by DSH PP, including IRFs with zero DSH PP, IRFs with a DSH PP less than 5 percent, IRFs with a DSH PP between 5 and less than 10 percent, IRFs with a DSH PP between 10 and 20 percent, and IRFs with a DSH PP greater than 20 percent.

The estimated impacts of each policy described in this final rule to the facility categories listed above are shown in the columns of Table 13. The description of each column is as follows:

- Column (1) shows the facility classification categories described above.
- Column (2) shows the number of IRFs in each category in our FY 2013 analysis file.
- Column (3) shows the number of cases in each category in our FY 2013 analysis file.
- Column (4) shows the estimated effect of the adjustment to the outlier threshold amount.
- Column (5) shows the estimated effect of the update to the IRF PPS payment rates, which includes a

productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.2 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and –(D)(iv) of the Act.

- Column (6) shows the estimated effect of the update to the IRF labor-related share and wage index, in a budget-neutral manner.
- Column (7) shows the estimated effect of the update to the CMG relative weights and average length of stay values, in a budget-neutral manner.
- Column (8) compares our estimates of the payments per discharge, incorporating all of the proposed policies reflected in this final rule for FY 2015 to our estimates of payments per discharge in FY 2014.

The average estimated increase for all IRFs is approximately 2.4 percent. This estimated net increase includes the effects of the RPL market basket increase factor for FY 2015 of 2.9 percent, reduced by a productivity adjustment of 0.5 percentage point in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and further reduced by 0.2 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and –(D)(iv) of the Act. It also includes the approximate 0.2 percent overall increase in estimated IRF outlier payments from the update to the outlier threshold amount. Since we are making the updates to the IRF wage index and the CMG relative weights in a budget-neutral manner, they will not be expected to affect total estimated IRF payments in the aggregate. However, as described in more detail in each section, they will be expected to affect the estimated distribution of payments among providers.

TABLE 13—IRF IMPACT TABLE FOR FY 2015

[Columns 4–9 in %]

Facility classification	Number of IRFs	Number of cases	Outlier	Adjusted market basket increase factor for FY 2015 ¹	FY 2015 CBA wage index and labor-share	CMG	Total percent change
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(9)
Total	1,142	389,157	0.2	2.2	0.0	0.0	2.4
Urban unit	732	179,336	0.3	2.2	0.0	0.0	2.6
Rural unit	165	26,444	0.3	2.2	0.0	0.1	2.6
Urban hospital	228	177,726	0.1	2.2	0.0	0.0	2.2
Rural hospital	17	5,651	0.1	2.2	–0.1	0.0	2.2
Urban For-Profit	335	165,971	0.1	2.2	–0.2	0.0	2.1
Rural For-Profit	64	12,484	0.2	2.2	–0.2	0.1	2.4
Urban Non-Profit	567	175,276	0.3	2.2	0.2	0.0	2.6
Rural Non-Profit	106	17,698	0.3	2.2	0.1	0.1	2.7
Urban Government	58	15,815	0.3	2.2	–0.1	0.0	2.4
Rural Government	12	1,913	0.4	2.2	–0.5	0.1	2.2
Urban	960	357,062	0.2	2.2	0.0	0.0	2.4

TABLE 13—IRF IMPACT TABLE FOR FY 2015—Continued
[Columns 4–9 in %]

Facility classification	Number of IRFs	Number of cases	Outlier	Adjusted market basket increase factor for FY 2015 ¹	FY 2015 CBSA wage index and labor-share	CMG	Total percent change
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(9)
Rural	182	32,095	0.3	2.2	−0.1	0.1	2.5
Urban by Region							
Urban New England	30	16,946	0.1	2.2	0.4	−0.1	2.6
Urban Middle Atlantic	141	58,438	0.2	2.2	0.8	0.0	3.1
Urban South Atlantic	138	64,756	0.2	2.2	−0.1	−0.1	2.2
Urban East North Central	180	53,400	0.2	2.2	−0.2	0.0	2.2
Urban East South Central	50	24,482	0.1	2.2	−0.5	−0.1	1.7
Urban West North Central	73	18,700	0.2	2.2	−0.4	0.0	2.0
Urban West South Central	173	71,028	0.2	2.2	−0.3	0.1	2.1
Urban Mountain	74	23,158	0.2	2.2	−0.7	0.0	1.7
Urban Pacific	101	26,154	0.4	2.2	0.6	0.0	3.2
Rural by Region							
Rural New England	5	1,270	0.2	2.2	0.0	−0.1	2.3
Rural Middle Atlantic	15	2,557	0.2	2.2	0.5	0.2	3.1
Rural South Atlantic	24	6,028	0.1	2.2	−0.1	0.1	2.4
Rural East North Central	31	5,244	0.3	2.2	−0.2	0.1	2.4
Rural East South Central	21	3,497	0.3	2.2	−0.1	0.1	2.5
Rural West North Central	27	3,460	0.5	2.2	0.5	0.1	3.3
Rural West South Central	48	8,974	0.2	2.2	−0.4	0.2	2.2
Rural Mountain	7	683	0.7	2.2	−0.1	0.0	2.8
Rural Pacific	4	382	0.9	2.2	1.2	0.0	4.4
Teaching Status							
Non-teaching	1,033	343,078	0.2	2.2	0.0	0.0	2.4
Resident to ADC less than 10%	60	31,090	0.2	2.2	0.3	−0.1	2.6
Resident to ADC 10%–19%	39	13,981	0.3	2.2	−0.1	−0.1	2.4
Resident to ADC greater than 19%	10	1,008	0.2	2.2	0.2	0.0	2.5
Disproportionate Share Patient Percentage (DSH PP)							
DSH PP = 0%	37	6,323	0.5	2.2	0.0	0.0	2.8
DSH PP less than 5%	185	65,137	0.2	2.2	0.1	0.1	2.6
DSH PP 5%–10%	333	130,367	0.2	2.2	−0.1	0.0	2.3
DSH PP 10%–20%	362	126,848	0.2	2.2	0.1	0.0	2.5
DSH PP greater than 20%	225	60,482	0.3	2.2	−0.1	−0.1	2.3

¹ This column reflects the impact of the RPL market basket increase factor for FY 2015 (2.9 percent), reduced by a 0.5 percentage point reduction for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, and reduced by 0.2 percentage points in accordance with paragraphs 1886(j)(3)(C) and (D) of the Act.

3. Impact of the Update to the Outlier Threshold Amount

The estimated effects of the update to the outlier threshold adjustment are presented in column 4 of Table 13. In the FY 2014 IRF PPS final rule (78 FR 47860), we used FY 2012 IRF claims data (the best, most complete data available at that time) to set the outlier threshold amount for FY 2014 so that estimated outlier payments would equal 3 percent of total estimated payments for FY 2014.

For this final rule, we are updating our analysis using FY 2013 IRF claims data and, based on this updated

analysis, we estimate that IRF outlier payments as a percentage of total estimated IRF payments are 2.8 percent in FY 2014. Thus, we are adjusting the outlier threshold amount in this final rule to set total estimated outlier payments equal to 3 percent of total estimated payments in FY 2015. The estimated change in total IRF payments for FY 2015, therefore, includes an approximate 0.2 percent increase in payments because the estimated outlier portion of total payments is estimated to increase from approximately 2.8 percent to 3 percent.

The impact of this outlier adjustment update (as shown in column 4 of Table

13) is to increase estimated overall payments to IRFs by about 0.2 percent. We estimate the largest increase in payments from the update to the outlier threshold amount to be 0.9 percent for rural IRFs in the Pacific region. We do not estimate that any group of IRFs would experience a decrease in payments from this proposed update.

4. Impact of the Market Basket Update to the IRF PPS Payment Rates

The estimated effects of the market basket update to the IRF PPS payment rates are presented in column 5 of Table 13. In the aggregate the update would result in a net 2.2 percent increase in

overall estimated payments to IRFs. This net increase reflects the estimated RPL market basket increase factor for FY 2014 of 2.9 percent, reduced by the 0.2 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act, and further reduced by a 0.5 percentage point productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act.

5. Impact of the CBSA Wage Index and Labor-Related Share

In column 6 of Table 13, we present the effects of the budget-neutral update of the wage index and labor-related share. The changes to the wage index and the labor-related share are discussed together because the wage index is applied to the labor-related share portion of payments, so the proposed changes in the two have a combined effect on payments to providers. As discussed in section VI.D. of this final rule, we will decrease the labor-related share from 69.494 percent in FY 2014 to 69.294 percent in FY 2015.

In the aggregate, since these updates to the wage index and the labor-related share are applied in a budget-neutral manner as required under section 1886(j)(6) of the Act, we do not estimate that these updates will affect overall estimated payments to IRFs. However, we estimate that these updates will have small distributional effects. For example, we estimate the largest increase in payments from the update to the CBSA wage index and labor-related share of 1.2 percent for rural IRFs in the Pacific region. We estimate the largest decrease in payments from the update to the CBSA wage index and labor-related share to be a 0.7 percent decrease for urban IRFs in the Mountain region.

6. Impact of the Update to the CMG Relative Weights and Average Length of Stay Values

In column 7 of Table 13, we present the effects of the budget-neutral update of the CMG relative weights and average length of stay values. In the aggregate, we do not estimate that these updates will affect overall estimated payments of IRFs. However, we do expect these updates to have small distributional effects. The largest estimated increase in payments is a 0.2 percent increase in rural Middle Atlantic and rural West South Central IRFs. Urban areas in New England, South Atlantic, and East South Central and rural New England are estimated to experience a 0.1 percent decrease in payments due to the CMG relative weights change.

7. Effects of the Changes to the Presumptive Compliance Method for Compliance Review Periods Beginning on or After October 1, 2014

As discussed in section VIII. of this final rule, we are making some additional changes to the presumptive compliance method for compliance review periods beginning on or after October 1, 2015. We do not estimate that the removal of the “amputation status” codes will have any significant financial effects on IRFs, as our data analysis indicates that IRFs are only using these codes for about 2 percent of cases and these codes are only being used to count patients towards the 60 percent rule in 0.3 percent of cases. Similarly, we do not estimate that the proposed exclusion of the non-specific Etiologic Diagnosis codes from the IGCs will have any significant financial effects on IRFs, as we estimate that IRFs will be able to switch to using the more specific codes that are available for the Etiologic Diagnoses instead.

We do, however, believe that there could be a financial effect on IRFs from the removal of the Unilateral Upper Extremity Amputations and Arthritis IGCs from the presumptive compliance method, as the removal of these IGCs from presumptively counting toward meeting the 60 percent rule compliance threshold could result in more IRFs failing to meet the requirements solely on the basis of the presumptive compliance method and being required to be evaluated using the medical review method. We estimate that these effects would be concentrated in approximately 10 percent of IRFs that admit a high number of patients with Unilateral Upper Extremity Amputation and Arthritis conditions, and that the effects would vary substantially among IRFs. As discussed in section X. of this final rule, we are providing IRFs with the ability to indicate on the IRF-PAI that a particular arthritis case meets the severity and prior treatment regulatory requirements, the purpose of which is to mitigate some of the financial effects for these IRFs while still allowing Medicare to ensure that the regulatory requirements are being met.

Comment: One commenter disagreed with our statement that the removal of non-specific codes from the presumptive methodology determination will not have a financial effect on IRFs because they will be able to change their coding practices to use more specific diagnosis codes instead. This commenter said that the information needed to report more specific diagnosis codes is not always available to IRFs.

Response: As we indicated in the FY 2014 IRF PPS final rule (78 FR 47860, 47887), we previously decided to allow some non-specific codes to count toward the presumptive methodology because we recognized that it would be extremely difficult for IRFs to gather the necessary information to code a more specific code in those particular cases. However, after careful analysis, we believe that the remaining non-specific codes that will not count toward an IRF’s presumptive compliance with the 60 percent rule are ones that the IRF can and should make every effort to code more specifically. Even if the necessary information to code more specifically is not available in the acute care medical record, we believe that the IRF should make every effort to obtain the necessary information to code more specifically. This is consistent with reduction in the use of non-specific codes for other Medicare settings.

8. Effects of New Therapy Information Section

Because the type, amount, frequency, and duration of therapy provided in IRFs is documented in detail in the IRF medical records as part of the requirements for meeting Medicare’s conditions of participation and IRF coverage requirements, we estimate that the additional costs incurred by IRFs for FY 2016 for the new proposed Therapy Information Section of the IRF-PAI would be based on the 4 additional minutes per IRF-PAI form to transfer the information from the IRF medical record to the IRF-PAI form. We estimate that this would result in an additional cost of \$1.2 million to all IRFs for FY 2016.

Comment: Many commenters said that our estimates of the overall costs to IRFs of the therapy data collection on the IRF-PAI are too low. They said that the costs of making the necessary modifications to their medical record systems and the training that will be required for therapists, nurses, and other clinical staff to ensure that they can record the data in a form and manner that will be compatible with the new data collection requirements will be substantial. In addition, there were comments regarding the added burden due to our original proposal to include the average number of minutes by mode and type of therapy for weeks 3 and beyond of a patient’s IRF stay.

Response: We appreciate the detailed comments that we received on this issue, and we understand, based on these comments, that the proposed collection of average number of minutes by mode and type of therapy for weeks 3 and beyond of a patient’s IRF stay

would require additional resources from the IRFs to operationalize. For this reason, we have withdrawn the proposal to collect the average number of minutes for weeks 3 and beyond. Instead, we will require IRFs to report on the IRF-PAI the total number of minutes of therapy provided to a patient, by mode and therapy discipline, for only week 1 and week 2 of the IRF stay. As described in section IX of this final rule, we believe that this will give us the minimum information that we need to develop future policy and to understand the nature of the services that Medicare is paying for under the IRF PPS, while also minimizing the costs to providers. We carefully considered commenters' suggestions that we add the collection of Concurrent Therapy as a mode and revise the definition of Group Therapy so that new data collection items would be consistent with the way in which facilities were already recording the information in the patient's medical record. We believe this will reduce the need for training and help to minimize burden. Finally, although we understand that updating specific software that IRFs use to collect this information can include additional costs, we view this as a provider business decision. Providers may always opt to use the IRVEN software supplied by CMS for collecting and submitting the IRF-PAI information. Given the revisions to the data collection described in section IX of this final rule, we believe that the cost estimate indicated for this data collection in the proposed rule is accurate.

9. Effects of Updates to the IRF QRP

As discussed in section XI.A. of this final rule and in accordance with section 1886(j)(7) of the Act, we will implement a 2 percentage point reduction in the FY 2015 increase factor for IRFs that have failed to report the required quality reporting data to us during the most recent IRF quality reporting period. In section XI.A of this final rule, we discuss how the 2 percentage point reduction will be applied. Only a few IRFs received the 2 percentage point reduction in the FY 2014 increase factor for failure to report the required quality reporting data last year, and we would anticipate that even fewer IRFs will receive the reduction for FY 2015 as they are now more familiar with the IRF QRP reporting requirements.

In sections XI.K and XI.L of this final rule, we have finalized our proposal to adopt a new data completion threshold as well as a new data accuracy validation policy. While we cannot

estimate the increase in the number of IRFs that will not meet our proposed requirements at this time, we believe that these finalized policies may increase the number of IRFs that receive a 2 percent point reduction to their FY annual increase factor for FY 2016 and beyond. Thus, we estimate that this policy will increase impact on overall IRF payments, by increasing the rate of non-compliance by an estimated 5 percent, for FY 2016 and beyond, decreasing the number of IRF providers that will receive their full annual increase factor for FY 2016 and beyond.

In this FY 2015 IRF PPS final rule, we finalized our proposal to adopt two new quality measures (MRSA and CDI), as well as to adopt a new data accuracy validation policy. Together, we estimate that these proposals will increase the cost to all IRF providers by \$852,238 annually, for an average cost to IRF providers of \$747.57 annually. This is an average increase of approximately 4.43 percent to all IRF providers over the FY 2014 burden. While we also proposed to adopt a data completion threshold policy, this policy, if finalized, will have no associated cost burden beyond that discussed in the first paragraph of this section (XI.C.9) of this final rule.

We intend to closely monitor the effects of this new quality reporting program on IRF providers and help perpetuate successful reporting outcomes through ongoing stakeholder education, national trainings, CMS Open Door Forums, and general and technical help desks. We did not receive any public comments with regard to this section of the proposed rule.

D. Alternatives Considered

The following is a discussion of the alternatives considered for the IRF PPS updates contained in this final rule.

Section 1886(j)(3)(C) of the Act requires the Secretary to update the IRF PPS payment rates by an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services. Thus, we did not consider alternatives to updating payments using the estimated RPL market basket increase factor for FY 2015. However, as noted previously in this final rule, section 1886(j)(3)(C)(ii)(I) of the Act requires the Secretary to apply a productivity adjustment to the market basket increase factor for FY 2015, and sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iv) of the Act require the Secretary to apply a 0.2 percentage point reduction to the market basket increase factor for FY 2015. Thus, in accordance with section 1886(j)(3)(C) of

the Act, we are updating the IRF federal prospective payments in this final rule by 2.2 percent (which equals the 2.9 percent estimated RPL market basket increase factor for FY 2015 reduced by 0.2 percentage points, and further reduced by a 0.5 percentage point productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act).

We considered maintaining the existing CMG relative weights and average length of stay values for FY 2015. However, in light of recently available data and our desire to ensure that the CMG relative weights and average length of stay values are as reflective as possible of recent changes in IRF utilization and case mix, we believe that it is appropriate to update the CMG relative weights and average length of stay values at this time to ensure that IRF PPS payments continue to reflect as accurately as possible the current costs of care in IRFs.

We considered updating facility-level adjustment factors for FY 2015. However, as discussed in more detail in section V.B. of this final rule, we believe that freezing the facility-level adjustments at FY 2014 levels for FY 2015 and all subsequent years (unless and until the data indicate that they need to be further updated) will allow us an opportunity to monitor the effects of the substantial changes to the adjustment factors for FY 2014, and will allow IRFs time to adjust to last year's changes.

We considered maintaining the existing outlier threshold amount for FY 2015. However, analysis of updated FY 2013 data indicates that estimated outlier payments would be lower than 3 percent of total estimated payments for FY 2015, by approximately 0.2 percent, unless we updated the outlier threshold amount. Consequently, we are adjusting the outlier threshold amount in this final rule to reflect a 0.2 percent increase thereby setting the total outlier payments equal to 3 percent, instead of 2.8 percent, of aggregate estimated payments in FY 2015.

We considered making no further changes to the presumptive compliance method in this final rule. However, to be consistent with the changes to the presumptive compliance method that we implemented in the FY 2014 IRF PPS final rule, and to correct some inadvertent omissions in last year's final rule, we believe it is important to make further changes in this final rule.

However, to ensure that the IRF-PAI item designed to mitigate some of the burden of additional medical reviews that could result from the changes to the presumptive compliance method is available on the IRF-PAI on the same

date or prior to the effective date of those changes, we are delaying the effective date of the changes to the presumptive compliance method. Both the changes to the presumptive compliance method that we finalized in the FY 2014 IRF PPS final rule and the additional changes to the presumptive compliance method that are finalized in this rule will become effective for compliance review periods beginning on or after October 1, 2015.

We considered not including the new Therapy Information Section on the

IRF-PAI. However, we believe that it is vitally important for Medicare to better understand the ways in which therapy services are currently being provided in IRFs and, most importantly, what services Medicare is paying for under the IRF benefit.

E. Accounting Statement

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf>), in Table 14, we have prepared an

accounting statement showing the classification of the expenditures associated with the provisions of this final rule. Table 14 provides our best estimate of the increase in Medicare payments under the IRF PPS as a result of the updates presented in this final rule based on the data for 1,142 IRFs in our database. In addition, Table 14 presents the costs associated with the new IRF quality reporting program and therapy reporting requirements for FY 2015.

TABLE 14—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
Change in Estimated Transfers from FY 2014 IRF PPS to FY 2015 IRF PPS	
Annualized Monetized Transfers	\$180 million.
From Whom to Whom?	Federal Government to IRF Medicare Providers.
Category	Costs
FY 2015 Cost to Updating the Quality Reporting Program	
Cost for IRFs to Submit Data for the Quality Reporting Program	\$852,238.
FY 2016 Cost for Therapy Data Collection	
Cost for IRFs to Submit Therapy Data	\$1.2 million.

F. Conclusion

Overall, the estimated payments per discharge for IRFs in FY 2015 are projected to increase by 2.4 percent, compared with the estimated payments in FY 2014, as reflected in column 9 of Table 13. IRF payments per discharge are estimated to increase by 2.4 percent in urban areas and by 2.5 percent in rural areas, compared with estimated FY 2014 payments. Payments per discharge to rehabilitation units are estimated to

increase 2.6 percent in urban and rural areas. Payments per discharge to freestanding rehabilitation hospitals are estimated to increase 2.2 percent in urban and rural areas.

Overall, IRFs are estimated to experience a net increase in payments as a result of the policies in final rule. The largest payment increase is estimated to be a 4.4 percent increase for rural IRFs located in the Pacific region.

Dated: July 24, 2014.

Marilyn Tavenner,
Administrator, Centers for Medicare & Medicaid Services.

Approved: July 30, 2014.

Sylvia M. Burwell,
Secretary, Department of Health and Human Services.

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Department of Health and Human Services

Center for Medicare & Medicaid Services

42 CFR Part 412

Medicare Program; Inpatient Psychiatric Facilities Prospective Payment System—Update for Fiscal Year Beginning October 1, 2014 (FY 2015); Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 412****[CMS–1606–F]****RIN 0938–AS08****Medicare Program; Inpatient Psychiatric Facilities Prospective Payment System—Update for Fiscal Year Beginning October 1, 2014 (FY 2015)****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule.

SUMMARY: This final rule will update the prospective payment rates for Medicare inpatient hospital services provided by inpatient psychiatric facilities (IPFs). These changes will be applicable to IPF discharges occurring during the fiscal year (FY) beginning October 1, 2014 through September 30, 2015. This final rule will also address implementation of ICD–10–CM and ICD–10–PCS codes; finalize a new methodology for updating the cost of living adjustment (COLA), and finalize new quality measures and reporting requirements under the IPF quality reporting program.

DATES: These regulations are effective on October 1, 2014.

FOR FURTHER INFORMATION CONTACT:

Dorothy Myrick or Jana Lindquist, (410) 786–4533, for general information.
Hudson Osgood, (410) 786–7897 or Bridget Dickensheets, (410) 786–8670, for information regarding the market basket and labor-related share.

Theresa Bean, (410) 786–2287, for information regarding the regulatory impact analysis. Rebecca Kliman, (410) 786–9723 or Jeffrey Buck, (410) 786–0407, for information regarding the inpatient psychiatric facility quality reporting program.

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Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

BBRA Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
CBSA Core-Based Statistical Area
CCR Cost-to-Charge Ratio

CAH Critical Access Hospital
DSM–IV–TR Diagnostic and Statistical Manual of Mental Disorders Fourth Edition—Text Revision
DRGs Diagnosis-Related Groups
FY Federal Fiscal Year (October 1 through September 30)
ICD–9–CM International Classification of Diseases, 9th Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, 10th Revision, Clinical Modification
ICD–10–PCS International Classification of Diseases, 10th Revision, Procedure Coding System
IPFs Inpatient Psychiatric Facilities
IPFQR Inpatient Psychiatric Facilities Quality Reporting
IRFs Inpatient Rehabilitation Facilities
LTCHs Long-Term Care Hospitals
MAC Medicare Administrative Contractor
MedPAR Medicare Provider Analysis and Review File
RPL Rehabilitation, Psychiatric, and Long-Term Care
RY Rate Year (July 1 through June 30)
TEFRA Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97–248)

I. Executive Summary**A. Purpose**

This final rule updates the prospective payment rates for Medicare inpatient hospital services provided by inpatient psychiatric facilities for discharges occurring during the fiscal year (FY) beginning October 1, 2014 through September 30, 2015.

B. Summary of the Major Provisions

In this final rule, we update the IPF PPS, as specified in 42 CFR 412.428. The updates include the following:

- The FY 2008-based Rehabilitation, Psychiatric, and Long Term Care (RPL) market basket update (currently estimated to be 2.9 percent) will be adjusted by a 0.3 percentage point reduction as required by section 1886(s)(2)(A)(ii) of the Social Security Act (the Act) and a reduction for economy-wide productivity (currently estimated to be 0.5 percentage point) as required by section 1886(s)(2)(A)(i) of the Act.
- The FY 2015 per diem rate is updated from \$713.19 to \$728.31.
- The electroconvulsive therapy payment is updated from \$307.04 to \$313.55.
- The fixed dollar loss threshold amount is updated from \$10,245 to \$8,755 in order to maintain outlier payments that are 2 percent of total IPF PPS payments.
- The national urban and rural cost-to-charge ratio (CCR) ceilings for FY 2015 is 1.6582 and 1.8590, respectively, and the national median CCR will be 0.6220 for rural IPFs and 0.4710 for

urban IPFs. These amounts are used in the outlier calculation to determine if an IPF's CCR is statistically accurate and for new providers without an established CCR.

- The cost of living adjustment factors for IPFs located in Alaska and Hawaii is updated using the approach finalized in the FY 2014 inpatient hospital prospective payment system (IPPS) final rule (78 FR 50985 through 50987).

In addition:

- We identify the ICD–10–CM/PCS codes that will be eligible for the MS–DRG and comorbidity payment adjustments under the IPF PPS. The effective date of those changes is October 1, 2015.

- We identify the ICD–9–CM/PCS codes that will be eligible for the MS–DRG and comorbidity payment adjustments under the IPF PPS.

- We use the best available hospital wage index and establish the wage

index budget-neutrality adjustment of 1.0002.

- We retain the 17 percent payment adjustment for IPFs located in rural areas, the 1.31 payment adjustment factor for IPFs with a qualifying emergency department, the coefficient value of 0.5150 for the teaching adjustment, and the MS–DRG adjustment factors and comorbidity adjustment factors currently being paid to IPFs in FY 2014.

C. Summary of Impacts

Provision description	
Total transfers	
FY 2015 IPF PPS payment rate update	The overall economic impact of this final rule is an estimated \$120 million in increased payments to IPFs during FY 2015.
Costs	
New quality reporting program requirements	The total costs in FY 2015 for IPFs as a result of the final new quality reporting requirements is estimated to be \$33,372,508.

II. Background

A. Annual Requirements for Updating the IPF PPS

In November 2004, we implemented the inpatient psychiatric facilities (IPF) prospective payment system (PPS) in a final rule that appeared in the November 15, 2004 **Federal Register** (69 FR 66922). In developing the IPF PPS, to ensure that the IPF PPS is able to account adequately for each IPF's case-mix, we performed an extensive regression analysis of the relationship between the per diem costs and certain patient and facility characteristics to determine those characteristics associated with statistically significant cost differences on a per diem basis. For characteristics with statistically significant cost differences, we used the regression coefficients of those variables to determine the size of the corresponding payment adjustments.

In that final rule, we explained that we believe it is important to delay updating the adjustment factors derived from the regression analysis until we have IPF PPS data that include as much information as possible regarding the patient-level characteristics of the population that each IPF serves. Therefore, we indicated that we did not intend to update the regression analysis and the patient- and facility-level adjustments until we complete that analysis. Until that analysis is complete, we stated our intention to publish a notice in the **Federal Register** each

spring to update the IPF PPS (71 FR 27041). We have begun the necessary analysis to make refinements to the IPF PPS using more current data to set the adjustment factors; however, we did not propose those refinements in the proposed rule and are not finalizing them in this final rule. Rather, as explained in section V.D.3 of this final rule, we expect that in future rulemaking, possibly for Fiscal Year (FY) 2017, we will be ready to propose potential refinements.

In the May 6, 2011 IPF PPS final rule (76 FR 26432), we changed the payment rate update period to a rate year (RY) that coincides with a FY update. Therefore, update notices are now published in the **Federal Register** in the summer to be effective on October 1. When proposing changes in IPF payment policy, a proposed rule would be issued in the spring and the final rule in the summer in order to be effective on October 1. For further discussion on changing the IPF PPS payment rate update period to a RY that coincides with a FY, see the IPF PPS final rule published in the **Federal Register** on May 6, 2011 (76 FR 26434 through 26435). For a detailed list of updates to the IPF PPS, see 42 CFR 412.428.

Our most recent IPF PPS annual update occurred in an August 1, 2013, **Federal Register** notice (78 FR 46734) (hereinafter referred to as the August 2013 IPF PPS notice) that set forth updates to the IPF PPS payment rates for FY 2014. That notice updated the

IPF PPS per diem payment rates that were published in the August 2012 IPF PPS notice (77 FR 47224) in accordance with our established policies.

B. Overview of the Legislative Requirements for the IPF PPS

Section 124 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) required the establishment and implementation of an IPF PPS. Specifically, section 124 of the BBRA mandated that the Secretary develop a per diem PPS for inpatient hospital services furnished in psychiatric hospitals and psychiatric units including an adequate patient classification system that reflects the differences in patient resource use and costs among psychiatric hospitals and psychiatric units.

Section 405(g)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) extended the IPF PPS to distinct part psychiatric units of critical access hospitals (CAHs).

Section 3401(f) of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by section 10319(e) of that Act and by section 1105(d) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (hereafter referred to as “the Affordable Care Act”) added subsections to section 1886 of the Act.

Section 1886(s)(1) of the Act titled “Reference to Establishment and Implementation of System” refers to section 124 of the BBRA, which relates to the establishment of the IPF PPS.

Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the RY beginning in 2012 (that is, a RY that coincides with a FY) and each subsequent RY. For the RY beginning in 2014 (that is, FY 2015), the current estimate of the productivity adjustment will be equal to 0.5 percentage point, which we are finalizing in this FY 2015 final rule.

Section 1886(s)(2)(A)(ii) of the Act requires the application of an “other adjustment” that reduces any update to an IPF PPS base rate by percentages specified in section 1886(s)(3) of the Act for the RY beginning in 2010 through the RY beginning in 2019. For the RY beginning in 2014 (that is, FY 2015), section 1886(s)(3)(C) of the Act requires the reduction to be 0.3 percentage point. We are finalizing that reduction in this FY 2015 IPF PPS final rule.

Section 1886(s)(4) of the Act requires the establishment of a quality data reporting program for the IPF PPS beginning in RY 2014. We proposed and finalized new requirements for quality reporting for IPFs in the “Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates” proposed rule published on May 10, 2013 (78 FR 27486, 27734 through 27744) and final rule published on August 19, 2013 (78 FR 50496, 50887 through 50903).

To implement and periodically update these provisions, we have published various proposed and final rules in the **Federal Register**. For more information regarding these rules, see the CMS Web site at <http://www.cms.hhs.gov/InpatientPsychFacilPPS/>.

C. General Overview of the IPF PPS

The November 2004 IPF PPS final rule (69 FR 66922) established the IPF PPS, as required by section 124 of the BBRA and codified at subpart N of part 412 of the Medicare regulations. The November 2004 IPF PPS final rule set forth the per diem Federal rates for the implementation year (the 18-month period from January 1, 2005 through June 30, 2006), and provided payment for the inpatient operating and capital costs to IPFs for covered psychiatric services they furnish (that is, routine, ancillary, and capital costs, but not costs of approved educational activities, bad

debts, and other services or items that are outside the scope of the IPF PPS). Covered psychiatric services include services for which benefits are provided under the fee-for-service Part A (Hospital Insurance Program) of the Medicare program.

The IPF PPS established the Federal per diem base rate for each patient day in an IPF derived from the national average daily routine operating, ancillary, and capital costs in IPFs in FY 2002. The average per diem cost was updated to the midpoint of the first year under the IPF PPS, standardized to account for the overall positive effects of the IPF PPS payment adjustments, and adjusted for budget-neutrality.

The Federal per diem payment under the IPF PPS is comprised of the Federal per diem base rate described above and certain patient- and facility-level payment adjustments that were found in the regression analysis to be associated with statistically significant per diem cost differences.

The patient-level adjustments include age, DRG assignment, comorbidities, and variable per diem adjustments to reflect higher per diem costs in the early days of an IPF stay. Facility-level adjustments include adjustments for the IPF’s wage index, rural location, teaching status, a cost-of-living adjustment for IPFs located in Alaska and Hawaii, and the presence of a qualifying emergency department (ED).

The IPF PPS provides additional payment policies for: outlier cases; interrupted stays; and a per treatment adjustment for patients who undergo electroconvulsive therapy (ECT). During the IPF PPS mandatory 3-year transition period, stop-loss payments were also provided; however, since the transition ended in 2008, these payments are no longer available.

A complete discussion of the regression analysis that established the IPF PPS adjustment factors appears in the November 2004 IPF PPS final rule (69 FR 66933 through 66936).

Section 124 of the BBRA did not specify an annual rate update strategy for the IPF PPS and was broadly written to give the Secretary discretion in establishing an update methodology.

Therefore, in the November 2004 IPF PPS final rule, we implemented the IPF PPS using the following update strategy:

- Calculate the final Federal per diem base rate to be budget-neutral for the 18-month period of January 1, 2005 through June 30, 2006.
- Use a July 1 through June 30 annual update cycle.
- Allow the IPF PPS first update to be effective for discharges on or after July 1, 2006 through June 30, 2007.

III. Provisions of the Proposed Regulations and Responses to Comments

On May 6, 2014, we published a proposed rule in the **Federal Register** (79 FR 26040) entitled Medicare Program; Inpatient Psychiatric Facilities Prospective Payment System—Update for Fiscal Year Beginning October 1, 2014 (FY 2015). The May 6, 2014 proposed rule (herein referred to as the FY 2015 IPF PPS proposed rule) set forth the proposed update to the prospective payment rates for Medicare inpatient hospital services provided by inpatient psychiatric facilities. In addition to the update, we proposed to:

- Adjust the FY 2008-based Rehabilitation, Psychiatric, and Long Term Care (RPL) market basket update by 0.3 percentage point reduction.
- Update the FY 2015 per diem rate from \$713.19 to \$727.67.
- Update the electroconvulsive therapy payment from \$307.04 to \$313.27.
- Update the fixed dollar loss threshold amount from \$10,245 to \$10,125.
- Update the cost of living adjustment factors for IPFs located in Alaska and Hawaii.

In addition, we proposed:

- Effective when ICD-10-CM/PCS becomes the required medical data code set for use on Medicare claims (which we now know will be October 1, 2015), the ICD-10-CM codes that would be eligible for the MS-DRG and comorbidity payment adjustments under the IPF PPS.
- ICD-9-CM/PCS codes that would be eligible for the MS-DRG and comorbidity payment adjustments.
- To use the best available hospital wage index and establish the wage index budget-neutrality adjustment.
- New Quality Measures for the FY 2016 Payment Determination and Subsequent Years (Patient Assessment of Experience of Care, Use of an Electronic Health Record).
- New Quality Measures for the FY 2017 Payment Determination and Subsequent Years (Influenza Immunization, Influenza Vaccination Coverage Among Healthcare Personnel, Tobacco Use Screening, and Tobacco Use Treatment Provided or Offered and Tobacco Use Treatment).
- Effective with FY 2017 payment determination, a requirement that facilities submit to CMS aggregate population counts for Medicare and non-Medicare discharges by age group, diagnostic group, and quarter, and sample size counts for measures, for which sampling is performed.

- To solicit recommendations from the public on additions and changes to the IPF quality reporting program in future years.

We provided for a 60-day comment period on the FY 2015 IPF PPS proposed rule. We received 28 public comments from hospital and hospital-based associations. In general, many commenters supported CMS' efforts to continue researching the possibility of an IPF-specific market basket and agreed that more work is necessary before any conclusions can be drawn regarding a proposal to develop an IPF-specific market basket. The majority of the comments were regarding the IPF quality reporting program (IPFQR Program). In general, the commenters varied as to their support for the newly proposed measures for the FY 2016 and FY 2017 payment determinations. Furthermore, many commenters offered recommendations on the IPFQR Program additions and changes for future IPFQR Program years. Summaries of the public comments received and our responses to those comments are provided in the appropriate sections in the preamble of this final rule.

IV. Changing the IPF PPS Payment Rate Update Period From a Rate Year to a Fiscal Year

Prior to RY 2012, the IPF PPS was updated on a July 1 through June 30 annual update cycle. Effective with RY 2012, we switched the IPF PPS payment rate update from a rate year that begins on July 1 and ends on June 30 to a period that coincides with a fiscal year. In order to transition from a RY to a FY, the IPF PPS RY 2012 covered a 15-month period from July 1 through September 30. As proposed and finalized, after RY 2012, the rate year update period for the IPF PPS payment rates and other policy changes begin on October 1 through September 30. Therefore, the update cycle for FY 2015 will be October 1, 2014 through September 30, 2015.

For further discussion of the 15-month market basket update for RY 2012 and changing the payment rate update period from a RY to a FY, we refer readers to the RY 2012 IPF PPS proposed rule (76 FR 4998) and the RY 2012 IPF PPS final rule (76 FR 26432).

V. Market Basket for the IPF PPS

A. Background

The input price index (that is, the market basket) that was used to develop the IPF PPS was the Excluded Hospital with Capital market basket. This market basket was based on 1997 Medicare cost report data and included data for

Medicare participating IPFs, inpatient rehabilitation facilities (IRFs), long-term care hospitals (LTCHs), cancer hospitals, and children's hospitals. Although "market basket" technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term "market basket" as used in this document refers to a hospital input price index.

Beginning with the May 2006 IPF PPS final rule (71 FR 27046 through 27054), IPF PPS payments were updated using a FY 2002-based market basket reflecting the operating and capital cost structures for IRFs, IPFs, and LTCHs (hereafter referred to as the Rehabilitation, Psychiatric, and Long-Term Care (RPL) market basket).

We excluded cancer and children's hospitals from the RPL market basket because these hospitals are not reimbursed through a PPS; rather, their payments are based entirely on reasonable costs subject to rate-of-increase limits established under the authority of section 1886(b) of the Act, which are implemented in regulations at § 413.40. Moreover, the FY 2002 cost structures for cancer and children's hospitals are noticeably different than the cost structures of the IRFs, IPFs, and LTCHs. A complete discussion of the FY 2002-based RPL market basket appears in the May 2006 IPF PPS final rule (71 FR 27046 through 27054).

In the RY 2012 IPF PPS proposed rule (76 FR 4998) and final rule (76 FR 26432), we proposed and finalized the use of a rebased and revised FY 2008-based RPL market basket to update IPF payments.

B. Development of an IPF-Specific Market Basket

In the May 1, 2009 IPF PPS notice (74 FR 20362), we expressed our interest in exploring the possibility of creating a stand-alone, or IPF-specific market basket that reflects the cost structures of only IPF providers. We noted that, of the available options, one would be to join the Medicare cost report data from freestanding IPF providers with data from hospital-based IPF providers. We indicated that an examination of the Medicare cost report data comparing freestanding and hospital-based IPFs revealed considerable differences between the two with respect to cost levels and cost structures. At that time, we stated that we were unable to fully explain the differences in costs between freestanding and hospital-based IPF providers. As a result, we felt that

further research was required and we solicited public comments for additional information that might help explain the reasons for the variations in costs and cost structures, as indicated by the cost report data (74 FR 20376). We summarized the public comments we received and our responses in the April 2010 IPF PPS notice (75 FR 23111 through 23113).

Since the April 2010 IPF PPS notice was published, we have made significant progress on the development of a stand-alone, or IPF-specific, market basket. Our research has focused on addressing several concerns regarding the use of the hospital-based IPF Medicare cost report data in the calculation of the major market basket cost weights. As discussed above, one concern is the cost level differences for hospital-based IPFs relative to freestanding IPFs that were not readily explained by the specific characteristics of the individual providers and the patients that they serve (for example, case mix, urban/rural status, teaching status). Furthermore, we are concerned about the variability in the cost report data among these hospital-based IPF providers and the potential impact on the market basket cost weights. These concerns led us to consider whether it is appropriate to use the universe of IPF providers to derive an IPF-specific market basket.

Recently, we have investigated the use of regression analysis to evaluate the effect of including hospital-based IPF Medicare cost report data in the calculation of cost distributions. We created preliminary regression models to try to explain variations in costs per day across both freestanding and hospital-based IPFs. These models were intended to capture the effects of facility-level and patient-level characteristics (for example, wage index, urban/rural status, ownership status, length-of-stay, occupancy rate, case mix, and Medicare utilization) on IPF costs per day. Using the results from the preliminary regression analyses, we identified smaller subsets of hospital-based and freestanding IPF providers where the predicted costs per day using the regression model closely matched the actual costs per day for each IPF. We then derived different sets of cost distributions using (1) these subsets of IPF providers and (2) the entire universe of freestanding and hospital-based IPF providers (including those IPFs for which the variability in cost levels remains unexplained). After comparing these sets of cost distributions, the differences were not substantial enough for us to conclude that the inclusion of those IPF providers with unexplained

variability in costs in the calculation of the cost distributions is a major cause for concern.

Another concern with incorporating the hospital-based IPF data in the derivation of an IPF-specific market basket is the complexity of the Medicare cost report data for these providers. The freestanding IPFs independently submit a Medicare cost report for their facilities, making it relatively straightforward to obtain the cost categories necessary to determine the major market basket cost weights. However, cost report data submitted for a hospital-based IPF are embedded in the Medicare cost report submitted for the entire hospital facility in which the IPF is located. Therefore, adjustments would have to be made to obtain cost weights that represent just the hospital-based IPF (as opposed to the hospital as a whole). For example, ancillary costs for services such as clinic services, drugs charged to patients, and emergency services for the entire hospital would need to be appropriately converted to a value that only represents the hospital-based IPF unit's cost. The preliminary method we have developed to allocate these costs is complex and still needs to be fully evaluated before we are ready to propose an IPF-specific market basket that would reflect both hospital-based and freestanding IPF data.

We would also note that our current preliminary data show higher labor costs for IPFs than observed for the 2008-based RPL market basket. This increase is driven primarily by higher compensation cost as a percent of total costs for IPFs. In our ongoing research, we are also evaluating the differences in salary costs as a percent of total costs for both hospital-based and freestanding IPFs. Salary costs are historically the largest component of the market baskets. Based on our review of the data reported on the applicable Medicare cost reports, our initial findings (using the preliminary allocation method as discussed above) have shown that the hospital-based IPF salary costs as a percent of total costs tend to be lower than those of freestanding IPFs. We are still evaluating the methods for deriving salary costs as a percent of total costs and need to further investigate the percentage of ancillary costs that should be appropriately allocated to the IPF salary costs for the hospital-based IPF, as discussed above.

Also, effective for cost reports beginning on or after May 1, 2010, we finalized a revised Hospital and Hospital Health Care Complex Cost Report, Form CMS 2552-10, (74 FR 31738). The report is available for

download from the CMS Web site at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/CostReports/Hospital-2010-form.html>. The revised Hospital and Hospital Health Care Complex Cost Report includes a new worksheet (Worksheet S-3, part V) that identifies the contract labor costs and benefit costs for the hospital/hospital care complex and is applicable to sub-providers and units. Our analysis of Worksheet S-3, part V shows significant underreporting of this data with fewer than 20 freestanding IPF providers reporting it. We encourage providers to submit this data so we can use it to calculate benefits and contract labor cost weights for the market basket. In the absence of this data, we will likely use the 2008-based RPL market basket methodology (76 FR 5003) to calculate the IPF benefit cost weight. This methodology calculates the ratio of the IPPS benefit cost weight to the IPPS salary cost weight and applies this ratio to the IPF salary cost weight in order to estimate the IPF benefit cost weight. For contract labor, in the absence of IPF-specific data, we will use a similar methodology.

For the reasons discussed above, while we believe we have made significant progress on the development of an IPF-specific market basket, we believe that further research is required at this time. As a result, we are not finalizing an IPF-specific market basket for FY 2015. We plan to complete our research during the remainder of this year and, provided that we are prepared to draw conclusions from our research, may propose an IPF-specific market basket for the FY 2016 rulemaking cycle. Public comments and responses on the IPF-specific market basket are summarized below.

Comment: Several commenters supported the development of a stand-alone IPF market basket. In addition, the commenters acknowledged that further analysis is required and asked that CMS make available the methodologies and data sources that are under consideration for the development of the stand-alone IPF market basket.

Response: As the commenters suggested, we will continue to research and analyze the development of an IPF-specific market basket that uses the most appropriate and reliable data sources and methods. We anticipate proposing to use an IPF-specific market basket in the FY 2016 IPF proposed rule and the public will have the opportunity to comment on our market basket methodology and data sources during the 60-day comment period following the publication of the proposed rule.

C. FY 2015 Market Basket Update

In the FY 2015 IPF PPS proposed rule (76 FR 26044), we proposed a FY 2015 IPF update of 2.0 percent, reflecting a 2.7 percent market basket update, less 0.4 percentage point MFP adjustment (as mandated in section 1886(s)(2)(A)(i) of the Act and further described in section 1886(b)(3)(B)(xi)(II) of the Act), less 0.3 percentage point adjustment (as mandated in Section 1886(s)(2)(A)(ii) of the Act). Furthermore, we also proposed that if more recent data are subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data, if appropriate, to determine the FY 2015 market basket update and MFP adjustment in the final rule.

Based on a more recent update for this FY 2015 IPF PPS final rule, that is, the IHS Global Insight, Inc. (IGI) second quarter 2014 forecast of the FY 2008-based RPL market basket, we are finalizing a market basket rate-of-increase of 2.9 percent (prior to the application of statutory adjustments). IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

As previously described in section I.B, section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the RY beginning in 2012 and each subsequent RY. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the "MFP adjustment").

The Bureau of Labor Statistics (BLS) publishes the official measure of private non-farm business MFP. We refer readers to the BLS Web site at <http://www.bls.gov/mfp> to obtain the BLS historical published MFP data. The MFP adjustment for FY 2015 applicable to the IPF PPS is derived using a projection of MFP that is currently produced by IGI. For a detailed description of the model currently used by IGI to project MFP, as well as a description of how the MFP adjustment is calculated, we refer readers to the FY 2012 IPPS/LTCH final rule (76 FR 51690 through 51692). Based on the most recent estimate, that is, IGI's second quarter 2014 forecast, the productivity adjustment for FY 2015 is 0.5 percentage point. Section 1886(s)(2)(A)(ii) of the Act also requires

the application of an “other adjustment” that reduces any update to an IPF PPS base rate by percentages specified in section 1886(s)(3) of the Act for rate years beginning in 2010 through the RY beginning in 2019. For the RY beginning in 2014 (that is, FY 2015), the reduction is 0.3 percentage point. We are implementing the productivity adjustment and “other adjustment” in this FY 2015 IPF PPS final rule.

In summary, we are basing the FY 2015 market basket update, which is used to determine the applicable percentage increase for the IPF payments, on the most recent estimate of the FY 2008-based RPL market basket (2.9 percent based on IGI’s second quarter 2014 forecast). We are then reducing this percentage increase by the current estimate of the MFP adjustment for FY 2015 of 0.5 percentage point (the 10-year moving average of MFP for the period ending FY 2015 based on IGI’s second quarter 2014 forecast). Following application of the MFP, we are further

reducing the applicable percentage increase by 0.3 percentage point, as required by section 1886(s)(3) of the Act. The final FY 2015 IPF update is 2.1 percent (2.9 percent market basket update, less 0.5 percentage point MFP adjustment, less 0.3 percentage point “other” adjustment).

D. Labor-Related Share

Due to variations in geographic wage levels and other labor-related costs, we believe that payment rates under the IPF PPS should continue to be adjusted by a geographic wage index, which would apply to the labor-related portion of the Federal per diem base rate (hereafter referred to as the labor-related share).

The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market. Based on our definition of the

labor-related share, we include in the labor-related share the sum of the relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Business Support Services, All Other: Labor-related Services, and a portion of the Capital-Related cost weight.

Therefore, to determine the labor-related share for the IPF PPS for FY 2015, we used the FY 2008-based RPL market basket cost weights relative importance to determine the labor-related share for the IPF PPS. This estimate of the FY 2015 labor-related share is based on IGI’s second quarter 2014 forecast, which is the same forecast used to derive the FY 2015 market basket update.

Table 1 below shows the FY 2015 relative importance labor-related share using the FY 2008-based RPL market basket along with the FY 2014 relative importance labor-related share.

TABLE 1—FY 2015 RELATIVE IMPORTANCE LABOR-RELATED SHARE AND THE FY 2014 RELATIVE IMPORTANCE LABOR-RELATED SHARE BASED ON THE FY 2008-BASED RPL MARKET BASKET

	FY 2014 relative importance labor-related share ¹	FY 2015 relative importance labor-related share ²
Wages and Salaries	48.394	48.271
Employee Benefits	12.963	12.936
Professional Fees: Labor-Related	2.065	2.058
Administrative and Business Support Services	0.415	0.415
All Other: Labor-Related Services	2.080	2.061
Subtotal	65.917	65.741
Labor-Related Portion of Capital Costs (46%)	3.577	3.553
Total Labor-Related Share	69.494	69.294

¹ Published in the FY 2014 IPF PPS notice (78 FR 46738) and based on IHS Global Insight, Inc.’s second quarter 2013 forecast of the FY 2008-based RPL market basket.

² Based on IHS Global Insight, Inc.’s second quarter 2014 forecast of the FY 2008-based RPL market basket.

The final labor-related share for FY 2015 is the sum of the FY 2015 relative importance of each labor-related cost category, and reflects the different rates of price change for these cost categories between the base year (FY 2008) and FY 2015. The sum of the relative importance for FY 2015 for operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Business Support Services, and All Other: Labor-related Services) is 65.741 percent, as shown in Table 1 above. The portion of Capital-related cost that is influenced by the local labor market is estimated to be 46 percent. Since the relative importance for Capital-Related Costs is 7.723 percent of the FY 2008-based RPL market basket in FY 2015, we take 46 percent of 7.723 percent to determine

the labor-related share of Capital-related cost for FY 2015. The result is 3.553 percent, which we add to 65.741 percent for the operating cost amount to determine the total labor-related share for FY 2015. Therefore, the labor-related share for the IPF PPS in FY 2015 is 69.294 percent. This labor-related share is determined using the same general methodology as employed in calculating all previous IPF labor-related shares (see, for example, 69 FR 66952 through 66953). The wage index and the labor-related share are reflected in budget-neutrality adjustments.

VI. Updates to the IPF PPS for FY 2015 (Beginning October 1, 2014)

The IPF PPS is based on a standardized Federal per diem base rate calculated from the IPF average per

diem costs and adjusted for budget-neutrality in the implementation year. The Federal per diem base rate is used as the standard payment per day under the IPF PPS and is adjusted by the patient-level and facility-level adjustments that are applicable to the IPF stay. A detailed explanation of how we calculated the average per diem cost appears in the November 2004 IPF PPS final rule (69 FR 66926).

A. Determining the Standardized Budget-Neutral Federal Per Diem Base Rate

Section 124(a)(1) of the BBRA required that we implement the IPF PPS in a budget-neutral manner. In other words, the amount of total payments under the IPF PPS, including any payment adjustments, must be projected

to be equal to the amount of total payments that would have been made if the IPF PPS were not implemented. Therefore, we calculated the budget-neutrality factor by setting the total estimated IPF PPS payments to be equal to the total estimated payments that would have been made under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97-248) methodology had the IPF PPS not been implemented. A step-by-step description of the methodology used to estimate payments under the TEFRA payment system appears in the November 2004 IPF PPS final rule (69 FR 66926).

Under the IPF PPS methodology, we calculated the final Federal per diem base rate to be budget-neutral during the IPF PPS implementation period (that is, the 18-month period from January 1, 2005 through June 30, 2006) using a July 1 update cycle. We updated the average cost per day to the midpoint of the IPF PPS implementation period (that is, October 1, 2005), and this amount was used in the payment model to establish the budget-neutrality adjustment.

Next, we standardized the IPF PPS Federal per diem base rate to account for the overall positive effects of the IPF PPS payment adjustment factors by dividing total estimated payments under the TEFRA payment system by estimated payments under the IPF PPS. Additional information concerning this standardization can be found in the November 2004 IPF PPS final rule (69 FR 66932) and the RY 2006 IPF PPS final rule (71 FR 27045). We then reduced the standardized Federal per diem base rate to account for the outlier policy, the stop loss provision, and anticipated behavioral changes. A complete discussion of how we calculated each component of the budget-neutrality adjustment appears in the November 2004 IPF PPS final rule (69 FR 66932 through 66933) and in the May 2006 IPF PPS final rule (71 FR 27044 through 27046). The final standardized budget-neutral Federal per diem base rate established for cost reporting periods beginning on or after January 1, 2005 was calculated to be \$575.95.

The Federal per diem base rate has been updated in accordance with applicable statutory requirements and 42 CFR 412.428 through publication of annual notices or proposed and final rules. These documents are available on the CMS Web site at <http://www.cms.hhs.gov/InpatientPsychFacilPPS/>. A detailed discussion on the standardized budget-neutral Federal per diem base rate and the electroconvulsive therapy (ECT) rate

appears in the August 2013 IPF PPS update notice (78 FR 46738 through 46739).

B. FY 2015 Update of the Federal Per Diem Base Rate and Electroconvulsive Therapy (ECT) Rate

In accordance with section 1886(s)(2)(A)(ii) of the Act, which requires the application of an “other adjustment,” described in section 1886(s)(3) of the Act (specifically, section 1886(s)(3)(C)) for FY 2014 that reduces the update to the IPF PPS base rate for the FY beginning in Calendar Year (CY) 2014, we are adjusting the IPF PPS update by a 0.3 percentage point reduction for FY 2015. In addition, in accordance with section 1886(s)(2)(A)(i) of the Act, which requires the application of the productivity adjustment that reduces the update to the IPF PPS base rate for the FY beginning in CY 2014, we are adjusting the IPF PPS update by a 0.5 percentage point reduction for FY 2015.

The current (that is, FY 2014) Federal per diem base rate is \$713.19 and the ECT base rate is \$307.04. For FY 2015, we are applying an update of 2.1 percent (that is the FY 2008-based RPL market basket increase for FY 2015 of 2.9 percent less the productivity adjustment of 0.5 percentage point less the 0.3 percentage point required under section 1886(s)(3)(C) of the Act), and the wage index budget-neutrality factor of 1.0002 (as discussed in section VI.C.1. of this final rule) to the FY 2014 Federal per diem base rate of \$713.19, yielding a Federal per diem base rate of \$728.31 for FY 2015. Similarly, we are applying the 2.1 percent payment update, and the 1.0002 wage index budget-neutrality factor to the FY 2014 ECT base rate, yielding an ECT base rate of \$313.55 for FY 2015.

As noted above, section 1886(s)(4) of the Act requires the establishment of a quality data reporting program for the IPF PPS beginning in FY 2014. We finalized new requirements for quality reporting for IPFs in the “Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates” proposed rule published on May 10, 2013 (78 FR 27486, 27734 through 27744) and final rule published on August 19, 2013 (78 FR 50496, 50887 through 50903). Section 1886(s)(4)(A)(i) of the Act requires that, for FY 2014 and each subsequent rate year, the Secretary shall reduce any annual update to a standard Federal rate for discharges occurring during the rate year by 2.0 percentage points for any IPF that does not comply with the quality data

submission requirements with respect to an applicable year. Therefore, we are applying a 2.0 percentage point reduction to the Federal per diem base rate and the ECT base rate as follows:

For IPFs that fail to submit quality reporting data under the IPFQR program, we are applying a 0.1 percent annual update (that is 2.1 percent reduced by 2 percentage points in accordance with section 1886(s)(4)(A)(ii) of the Act) and the wage index budget-neutrality factor of 1.0002 to the FY 2014 Federal per diem base rate of \$713.19, yielding a Federal per diem base rate of \$714.05 for FY 2015.

Similarly, we are applying the 0.1 percent annual update and the 1.0002 wage index budget-neutrality factor to the FY 2014 ECT base rate of \$307.04, yielding an ECT base rate of \$ 307.41 for FY 2015.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50496), we adopted two new measures for the FY 2016 payment determination and subsequent years for the IPFQR Program. We also finalized a request for voluntary information whereby IPFs will be asked to provide information on the patient experience of care survey. For the FY 2016 payment determination and subsequent years, we are adding two new measures to those already adopted for the FY 2016 payment determination and subsequent years. For the FY 2017 payment determination and subsequent years, we are adopting four new measures. Public comments and responses on the FY 2015 updates to the IPF PPS are summarized below.

Comment: One commenter did not believe the proposed FY 2015 update and its associated projected payments to Michigan IPFs was an adequate increase as it failed to cover the cost of medical inflation.

Response: CMS proposed applying an update of 2.0 percent (79 FR 26044) to the FY 2014 Federal per diem base rate of \$713.19, as well as a 1.0003 wage index budget-neutrality factor, yielding a proposed Federal per diem base rate of \$727.67 for FY 2015 (79 FR 26046). The proposed 2.0 percent update reflected the proposed increase in the FY2008-based RPL market basket for FY 2015, as required by statute, of 2.7 percent less the proposed productivity adjustment of 0.4 percentage point (as mandated in section 1886(s)(2)(A)(i) of the Act and further described in section 1886(b)(3)(B)(xi)(II) of the Act)) and less the 0.3 percentage point adjustment (as mandated in Section 1886(s)(2)(A)(ii) of the Act).

As discussed in section III.C and section VI.C.1 of this final rule, we are

finalizing an update of 2.1 percent to the FY 2014 Federal per diem base rate as well as a 1.0002 wage index budget-neutrality factor for FY 2015. The final 2.1 percent FY 2015 update reflects the 2.9 percent market basket update less the productivity adjustment of 0.5 percentage point (as mandated in section 1886(s)(2)(A)(i) of the Act and further described in section 1886(b)(3)(B)(xi)(II) of the Act)) and less the 0.3 percentage point adjustment (as mandated in Section 1886(s)(2)(A)(ii) of the Act).

VII. Update of the IPF PPS Adjustment Factors

A. Overview of the IPF PPS Adjustment Factors

The IPF PPS payment adjustments were derived from a regression analysis of 100 percent of the FY 2002 MedPAR data file, which contained 483,038 cases. For a more detailed description of the data file used for the regression analysis, see the November 2004 IPF PPS final rule (69 FR 66935 through 66936). While we have since used more recent claims data to simulate payments to set the fixed dollar loss threshold amount for the outlier policy and to assess the impact of the IPF PPS updates, we continue to use the regression-derived adjustment factors established in 2005 for FY 2015.

As we stated previously, we have begun an analysis of more current IPF claims and cost report data; however, as we stated in the FY 2015 IPF PPS proposed rule, we are not making refinements to the IPF PPS in this final rule. Once our analysis is complete, we will propose to update the adjustment factors in a future notice of proposed rulemaking. However, we continue to monitor claims and payment data independently from cost report data to assess issues, to determine whether changes in case-mix or payment shifts have occurred among freestanding governmental, non-profit and private psychiatric hospitals, and psychiatric units of general hospitals, and CAHs and other issues of importance to IPFs.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section 212 of PAMA, titled “Delay in Transition from ICD–9 to ICD–10 Code Sets,” provides that “[t]he Secretary of Health and Human Services may not, prior to October 1, 2015, adopt ICD–10 code sets as the standard for code sets under section 1173(c) of the Social Security Act (42 U.S.C. 1320d–2(c)) and section 162.1002 of title 45, Code of Federal Regulations.” At the time we sent the proposed rule to the **Federal**

Register for publication, the Secretary had not yet announced when the new ICD–10 compliance date would be. Therefore we indicated that, in light of PAMA, the effective date of changes from ICD–9 to ICD–10 for the IPF PPS would be the date when ICD–10 becomes the required medical data code set for use on Medicare claims, whenever that date may be.

On May 1, 2014, the Department announced that, in light of section 212 of PAMA, “the U.S. Department of Health and Human Services expects to release an interim final rule in the near future that will include a new compliance date that would require the use of ICD–10 beginning October 1, 2015. The rule will also require HIPAA covered entities to continue to use ICD–9–CM through September 30, 2015.” Therefore, in light of this announcement, we will continue to require use of the ICD–9–CM codes for reporting the MS–DRG and comorbidity adjustment factors for IPF services through FY 2015 and we will require the use of ICD–10 codes beginning October 1, 2015.

B. Patient-Level Adjustments

The IPF PPS includes payment adjustments for the following patient-level characteristics: Medicare Severity diagnosis related groups (MS–DRGs) assignment of the patient’s principal diagnosis, selected comorbidities, patient age, and the variable per diem adjustments.

1. Adjustment for MS–DRG Assignment

We believe it is important to maintain the same diagnostic coding and DRG classification for IPFs that are used under the IPPS for providing psychiatric care. For this reason, when the IPF PPS was implemented for cost reporting periods beginning on or after January 1, 2005, we adopted the same diagnostic code set (ICD–9–CM) and DRG patient classification system (that is, the CMS DRGs) that were utilized at the time under the IPPS. In the May 2008 IPF PPS notice (73 FR 25709), we discussed CMS’s effort to better recognize resource use and the severity of illness among patients. CMS adopted the new MS–DRGs for the IPPS in the FY 2008 IPPS final rule with comment period (72 FR 47130). In the 2008 IPF PPS notice (73 FR 25716) we provided a crosswalk to reflect changes that were made under the IPF PPS to adopt the new MS–DRGs. For a detailed description of the mapping changes from the original DRG adjustment categories to the current MS–DRG adjustment categories, we refer readers to the May 2008 IPF PPS notice (73 FR 25714).

The IPF PPS includes payment adjustments for designated psychiatric DRGs assigned to the claim based on the patient’s principal diagnosis. The DRG adjustment factors were expressed relative to the most frequently reported psychiatric DRG in FY 2002, that is, DRG 430 (psychoses). The coefficient values and adjustment factors were derived from the regression analysis. Mapping the DRGs to the MS–DRGs resulted in the current 17 IPF–MS–DRGs, instead of the original 15 DRGs, for which the IPF PPS provides an adjustment. For FY 2015, as we did in FY 2013 (77 FR 47231) and FY 2014 (78 FR 46741 through 46741), we proposed to make a payment adjustment for psychiatric diagnoses that group to one of the 17 MS–IPF–DRGs listed in Table 2. Psychiatric principal diagnoses that do not group to one of the 17 designated DRGs would still receive the Federal per diem base rate and all other applicable adjustments, but the payment would not include a DRG adjustment.

In the Standards for Electronic Transaction final rule, published in the **Federal Register** on August 17, 2000 (65 FR 50312), the Department adopted the International Classification of Diseases, 9th Revision, Clinical Modification (ICD–9–CM) as the HIPAA designated code set for reporting diseases, injuries, impairments, other health related problems, their manifestations, and causes of injury. Therefore, on January 1, 2005 when the IPF PPS began, we used ICD–9–CM as the designated code set for the IPF PPS. IPF claims with a principal diagnosis included in Chapter Five of the ICD–9–CM are paid the Federal per diem base rate and all other applicable adjustments, including any applicable DRG adjustment. However, as we indicated in the FY 2014 IPF PPS notice (78 FR 46741), in accordance with the requirements of the final rule that delayed the ICD–10 compliance date from October 1, 2014, published in the **Federal Register** on September 5, 2012 (77 FR 54664), we will be discontinuing the use of ICD–9–CM codes. In the FY 2015 IPF PPS proposed rule we proposed the conversion of ICD–9–CM to ICD–10–CM/PCS codes. In light of PAMA, we proposed the effective date would be when ICD–10 becomes the required medical data code set for use on Medicare claims. Now that the Secretary has announced October 1, 2015 as the new compliance date for ICD–10, we will continue to require the use of the ICD–9–CM codes for reporting the MS–DRGs for IPF services through FY 2015, and we will require the use of ICD–10 codes beginning October 1, 2015.

The ICD-10-CM/PCS coding guidelines are available through the CMS Web site at: www.cms.gov/Medicare/Coding/ICD10/downloads/pcs_2012_guidelines.pdf and <http://www.cms.gov/Medicare/Coding/ICD10/index.html?redirect=/ICD10> or on the Center for Disease Control and Prevention (CDC's) Web site at www.cdc.gov/nchs/data/icd10/10cmguidelines2012.pdf.

Every year, changes to the ICD-10-CM and the ICD-10-PCS coding system will be addressed in the IPPS proposed and final rules. The changes to the codes are effective October 1 of each year and must be used by acute care hospitals as well as other providers to report diagnostic and procedure information. The IPF PPS has always incorporated ICD-9-CM coding changes made in the annual IPPS update and will continue to do so for the ICD-10-CM and ICD-10-PCS coding changes. We will continue to publish coding changes in a Transmittal/Change Request, similar to how coding changes are announced by the IPPS and LTCH PPS. The coding changes relevant to the IPF PPS are also published in the IPF PPS proposed and final rules, or in IPF PPS update notices. In 42 CFR 412.428(e), we indicate that CMS will publish information pertaining to the annual update for the IPF PPS, which includes describing the ICD-9-CM coding changes and DRG classification changes discussed in the annual update to the hospital IPPS regulations. We proposed to update § 412.428(e) to indicate that we will describe the ICD-10-CM coding changes and DRG classification changes discussed in the annual update to the hospital IPPS regulations when ICD-10-CM/PCS becomes the required medical data code set for use on Medicare claims. Now that we know the ICD-10 compliance date will be October 1, 2015, we will include revised § 412.428(e) in the FY 2016 IPF PPS update, which will be effective on October 1, 2015.

The ICD-9-CM coding changes are reflected in the FY 2015 GROUPER, Version 32.0, effective for IPPS discharges occurring on or after October 1, 2014 through September 30, 2015. The GROUPER Version 32.0 software package assigns each case to an MS-DRG on the basis of the diagnosis and procedure codes and demographic information (that is, age, sex, and discharge status). The Medicare Code Editor (MCE) version 32.0 has also been updated for IPPS discharges on or after October 1, 2014.

The IPF PPS has always used the same GROUPER and MCE as the IPPS. We have posted a Definitions Manual of the ICD-10 MS-DRGs Version 31.0-R (an updated ICD-10 MS-DRGs version 31.0) on the ICD-10 MS-DRG Conversion Project Web site at: <http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html>. We also prepared a document that describes changes made from Version 31.0 to Version 31.0-R. We will continue to share ICD-10-MS-DRG conversion activities with the public through this Web site.

The MS-DRGs were converted so that the MS-DRG assignment logic uses ICD-10-CM/PCS codes directly. When a provider submits a claim for discharges, the ICD-10-CM/PCS diagnosis and procedure codes will be assigned to the correct MS-DRG. The MS-DRGs were converted with a single overarching goal: That MS-DRG assignment for a given patient record is the same after ICD-10-CM implementation as it would be if the same record had been coded in ICD-9-CM and submitted prior to ICD-10-CM/PCS implementation. This goal is referred to as replication, and every effort was made to achieve this goal.

The General Equivalence Mappings (GEMs) were used to assist in converting the ICD-9-CM-based MS-DRGs to ICD-10-CM/PCS. The majority of ICD-9-CM codes (greater than 80 percent) have straightforward translation alternative(s) in ICD-10-CM/PCS, where the diagnoses or procedures classified to a

given ICD-9-CM code are replaced by a number of (typically more specific) ICD-10-CM/PCS codes and assigned to the same MS-DRG as the ICD-9-CM code they are replacing. Further information on the assessment of ICD-10-CM/PCS MS-DRGs and financial impact can be found on the CMS ICD-10 Web site at: <http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html>.

Questions concerning the MS-DRGs should be directed to Patricia E. Brooks, Co-Chairperson, ICD-10-CM Coordination and Maintenance Committee, CMS, Center for Medicare Management, Hospital and Ambulatory Policy Group, Division of Acute Care, patricia.brooks2@cms.hhs.gov, Mailstop C4-08-06, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Use of the General Equivalence Mappings To Assist in Direct Conversion

For the FY 2015 update, we are not making changes to the MS-IPF-DRG adjustment factors. That is, we do not intend to re-run the regression analysis to update the 17 IPF MS-DRG adjustment factors. The General Equivalence Mappings (GEMs) were used to assist in converting the ICD-9-CM-based MS-DRGs to ICD-10-CM/PCS. For this update, we are using the ICD-10-CM/PCS codes that will be used for the MS-DRG payment adjustment. Further information for the ICD-10-CM/PCS MS-DRG conversion project can be found on the CMS ICD-10-CM Web site at <http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html>.

Final Rule Action: The MS-IPF-DRG adjustment factors (as shown in Table 2) will continue to be paid for discharges occurring in FY 2015. The MS-IPF-DRG adjustment factors will be updated on October 1, 2014, using the ICD-9-CM/PCS code set. The conversion of ICD-9-CM/PCS codes to ICD-10-CM/PCS codes for the IPF PPS in this final rule will go into effect on October 1, 2015.

TABLE 2—FY 2015 CURRENT MS-IPF-DRGS APPLICABLE FOR THE PRINCIPAL DIAGNOSIS ADJUSTMENT

MS-DRG	MS-DRG descriptions	Adjustment factor
056	Degenerative nervous system disorders w MCC	1.05
057	Degenerative nervous system disorders w/o MCC	1.05
080	Nontraumatic stupor & coma w MCC	1.07
081	Nontraumatic stupor & coma w/o MCC	1.07
876	O.R. Procedure w principal diagnoses of mental illness	1.22
880	Acute adjustment reaction & psychosocial dysfunction	1.05
881	Depressive neuroses	0.99
882	Neuroses except depressive	1.02
883	Disorders of personality & impulse control	1.02
884	Organic disturbances & mental retardation	1.03

TABLE 2—FY 2015 CURRENT MS-IPF-DRGS APPLICABLE FOR THE PRINCIPAL DIAGNOSIS ADJUSTMENT—Continued

MS-DRG	MS-DRG descriptions	Adjustment factor
885	Psychoses	1.00
886	Behavioral & developmental disorders	0.99
887	Other mental disorder diagnoses	0.92
894	Alcohol/drug abuse or dependence, left AMA	0.97
895	Alcohol/drug abuse or dependence w rehabilitation therapy	1.02
896	Alcohol/drug abuse or dependence w/o rehabilitation therapy w MCC	0.88
897	Alcohol/drug abuse or dependence w/o rehabilitation therapy w/o MCC	0.88

2. Payment for Comorbid Conditions

The intent of the comorbidity adjustments is to recognize the increased costs associated with comorbid conditions by providing additional payments for certain concurrent medical or psychiatric conditions that are expensive to treat. In the May 2011 IPF PPS final rule (76 FR 26451 through 26452), we explained that the IPF PPS includes 17 comorbidity categories and identified the new, revised, and deleted ICD-9-CM diagnosis codes that generate a comorbid condition payment adjustment under the IPF PPS for RY 2012 (76 FR 26451).

Comorbidities are specific patient conditions that are secondary to the patient's principal diagnosis and that require treatment during the stay. Diagnoses that relate to an earlier episode of care and have no bearing on the current hospital stay are excluded and must not be reported on IPF claims. Comorbid conditions must exist at the time of admission or develop subsequently, and affect the treatment received, length of stay (LOS), or both treatment and LOS.

For each claim, an IPF may receive only one comorbidity adjustment within a comorbidity category, but it may receive an adjustment for more than one comorbidity category. Current billing instructions require IPFs to enter the full, that is, the complete ICD-9-CM codes for up to 24 additional diagnoses if they co-exist at the time of admission or develop subsequently and impact the treatment provided. Billing instructions will require that IPFs enter the full ICD-10-CM/PCS codes. The effective date of this change will be October 1, 2015.

The comorbidity adjustments were determined based on the regression analysis using the diagnoses reported by IPFs in FY 2002. The principal diagnoses were used to establish the DRG adjustments and were not accounted for in establishing the comorbidity category adjustments, except where ICD-9-CM “code first” instructions apply. As we explained in the May 2011 IPF PPS final rule (76 FR

265451), the “code first” rule applies when a condition has both an underlying etiology and a manifestation due to the underlying etiology. For these conditions, ICD-9-CM has a coding convention that requires the underlying conditions to be sequenced first followed by the manifestation. Whenever a combination exists, there is a “use additional code” note at the etiology code and a “code first” note at the manifestation code.

The same principle holds for ICD-10-CM as for ICD-9-CM. Whenever a combination exists, there is a “use additional code” note in the ICD-10-CM codebook pertaining to the etiology code, and a “code first” code pertaining to the manifestation code. We provide a “code first” table in Addendum C of this final rule for reference that highlights the same or similar manifestation codes where the “code first” instructions apply in ICD-10-CM that were present in ICD-9-CM. In the “code first” table, pertaining to ICD-10-CM codes F02.80, F02.81 and F05, where individual examples of possible etiologies are listed in the codebook, in the interest of inclusiveness, all ICD-10-CM examples are included in addition to the comparable ICD-10-CM translations of examples listed in the ICD-9-CM codebook for the same manifestations. Also, in the interest of inclusiveness, an ICD-10-CM manifestation code F45.42 “Pain disorder with related psychological factors,” is included in the IPF PPS “code first” table even though it contains a “code also” instruction rather than a “code first” instruction, but is included in this version of the table for information purposes only. The list of ICD-10-CM codes that we identified as “code first” can be located in Addendum C in this final rule.

As discussed in the MS-DRG section, it is our policy to maintain the same diagnostic coding set for IPFs that is used under the IPPS for providing the same psychiatric care. The 17 comorbidity categories formerly defined using ICD-9-CM codes have been converted to ICD-10-CM/PCS. The goal

for converting the comorbidity categories is referred to as replication, meaning that the payment adjustment for a given patient encounter is the same after ICD-10-CM implementation as it will be if the same record had been coded in ICD-9-CM and submitted prior to ICD-10-CM/PCS implementation. All conversion efforts were made with the intent of achieving this goal. The effective date of this change is October 1 2015.

Direct Conversion of Comorbidity Categories

We converted the ICD-9-CM codes for the IPF PPS Comorbidity Payment Adjustment Categories to ICD-10-CM/PCS codes. When an IPF submits a claim for discharges the ICD-10-CM/PCS codes will be assigned to the correct comorbidity categories. The same method of direct conversion to ICD-10-CM/PCS for replication of ICD-9-CM based payment applications has been implemented by policy groups throughout CMS to convert applications to ICD-10-CM/PCS, including the MS-DRGs.

Use of the General Equivalence Mappings to Assist in Direct Conversion

As with the other policy groups mentioned above, the General Equivalence Mappings (GEMs) were used to assist in converting ICD-9-CM-based applications to ICD-10-CM/PCS. Further information concerning the GEMs can be found on the CMS ICD-10 Web site at: <http://www.cms.gov/Medicare/Coding/ICD10/2014-ICD-10-CM-and-GEMs.html>.

The majority of ICD-9-CM codes (greater than 80 percent) have straightforward translation alternative(s) in ICD-10-CM/PCS, where the diagnoses or procedures classified to a given ICD-9-CM code are replaced by a number of possibly more specific ICD-10-CM/PCS codes, and those ICD-10-CM/PCS codes capture the intent of the payment policy.

In rare instances, ICD-10-CM has discontinued an area of detail in the classification. For example, this is the case with the concept of “malignant

hypertension” in the Cardiac Conditions comorbidity category. Malignant hypertension is no longer classified separately in codes that specify heart failure, such as ICD-9-CM code 404.03 Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage V or end-stage renal disease. This code, in the Cardiac Conditions comorbidity category, has no corresponding code in the ICD-10-CM Cardiac Conditions comorbidity category. Instead, all subtypes of hypertension in the presence of heart disease or chronic kidney disease are classified to a single code in ICD-10-CM that specifies the level of heart and kidney function, such as I13.2 Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease. Discussed below are the comorbidity categories where the crosswalk between ICD-9-CM and ICD-10-CM diagnosis codes is less than straightforward. For instance, in some cases, the use of combination codes in one code set is represented as two separate codes in the other code set.

Conversion of Gangrene and Uncontrolled Diabetes Mellitus With or Without Complications Comorbidity Categories

In the Gangrene comorbidity category, there are new ICD-10-CM combination codes not present in ICD-9-CM. Therefore, we are including many more ICD-10-CM codes in the comorbidity definitions than were included using ICD-9-CM codes so that the comorbidity category using ICD-10-CM codes is a complete and accurate replication of the category using ICD-9-CM codes.

The ICD-9-CM version of the comorbidity category Uncontrolled Diabetes Mellitus With or Without Complications contains combination codes with extra information that is not relevant to the clinical intent of the category. All patients with uncontrolled diabetes are eligible for the payment adjustment, regardless of whether they have additional diabetic complications. The diagnosis of uncontrolled diabetes is coded separately in ICD-10-CM. As a result, only two ICD-10-CM codes are needed to achieve complete and accurate replication of the comorbidity category definition using ICD-9-CM codes.

Conversion of the Gangrene Comorbidity Category

Currently, two ICD-9-CM codes are used for the Gangrene comorbidity category: 440.24 Atherosclerosis of

native arteries of the extremities with gangrene and 785.4 Gangrene.

The first code, 440.24, is a combination code and specifies patients with underlying peripheral vascular disease and a current acute manifestation of gangrene. This is the only ICD-9-CM combination code that specifies gangrene in addition to the underlying cause. Also, a number of ICD-10-CM codes exist for gangrene and they are all included in the ICD-10-CM comorbidity category. The ICD-10-CM codes specify anatomic site in more detail. An example is given below:

- I70.261 Atherosclerosis of native arteries of extremities with gangrene, right leg
- I70.262 Atherosclerosis of native arteries of extremities with gangrene, left leg
- I70.263 Atherosclerosis of native arteries of extremities with gangrene, bilateral legs
- I70.268 Atherosclerosis of native arteries of extremities with gangrene, other extremity

In addition, many ICD-10-CM codes specify gangrene in combination with diabetes. We are including these codes in the comorbidity category to ensure that a patient with diabetes complicated by gangrene receives the same payment adjustment for the condition when it is coded in ICD-10 as if it had been coded in ICD-9-CM.

Conversion of the Uncontrolled Diabetes Mellitus With or Without Complications Comorbidity Category

Where ICD-9-CM uses combination codes for uncontrolled diabetes, ICD-10-CM classifies diabetes that is out of control in a separate, standalone code. Unlike ICD-9-CM, ICD-10-CM does not have additional codes that specify out of control diabetes in combination with a complication such as, for example, diabetic chronic kidney disease. The result is that the comorbidity category Uncontrolled Diabetes Mellitus With or Without Complications is simpler to define using ICD-10-CM codes than ICD-9-CM codes.

ICD-10-CM has changed the classification of a diagnosis of uncontrolled diabetes in two ways that affect conversion of the Uncontrolled Diabetes comorbidity category:

1. ICD-10-CM no longer uses the term “uncontrolled” in reference to diabetes.
2. ICD-10-CM classifies diabetes that is poorly controlled in a separate, standalone code.

ICD-10-CM does not use the term “uncontrolled” in codes that classify diabetes patients. Instead, ICD-10-CM codes specify diabetes “with

hyperglycemia” as the new terminology for classifying patients whose diabetes is “poorly controlled” or “inadequately controlled” or “out of control.” We believe these are appropriate codes to capture the intent of the Uncontrolled Diabetes comorbidity category.

Therefore, to ensure that all patients who qualified for the Uncontrolled Diabetes comorbidity payment adjustment using ICD-9-CM codes will also qualify for the payment adjustment using ICD-10-CM codes, we propose that two ICD-10-CM codes specifying diabetes with hyperglycemia will be used for the payment adjustment for Uncontrolled Diabetes Mellitus With or Without Complications: E10.65 Type 1 diabetes mellitus with hyperglycemia, and E11.65 Type 2 diabetes mellitus with hyperglycemia.

Other Differences between ICD-9-CM and ICD-10-CM Affecting Conversion of Comorbidity Categories

Two other comorbidity categories in the IPF PPS required careful review and additional formatting of the corresponding ICD-10-CM codes in order to replicate the clinical intent of the comorbidity category. In the Drug and/or Alcohol Induced Mental Disorders comorbidity category and the Poisoning comorbidity category, significant structural changes in the way that comparable codes are classified in ICD-10-CM made it more difficult to list the diagnoses in ICD-10-CM code ranges, as was possible in ICD-9-CM. Because comparable codes are not classified contiguously in the ICD-10-CM classification scheme, the resulting list of codes for this comorbidity category is much longer than the comorbidity category using ICD-9-CM codes.

Conversion of the Drug and/or Alcohol Induced Mental Disorders Comorbidity Category

ICD-10-CM has changed the classification of applicable conditions in two ways that affect conversion of the Drug and/or Alcohol Induced Mental Disorders comorbidity category:

1. ICD-10-CM does not use the term “pathological” in reference to drug or alcohol intoxication, rather it only uses the phrase “with intoxication.”
2. ICD-10-CM contains separate, detailed codes for specific drug-induced manifestations of mental disorder. ICD-10-CM codes specify the particular drug and whether the pattern of use is documented as use, abuse, or dependence.

First, this comorbidity category currently contains ICD-9-CM code 292.2 Pathological drug intoxication. To

ensure that all patients who qualified for the comorbidity payment adjustment under ICD-9-CM code 292.2 will also qualify under the ICD-10-CM version of the same comorbidity category, the 89 ICD-10-CM codes specifying “with intoxication” will qualify for the payment adjustment. An example of the ICD-10-CM codes for a diagnosis of cocaine abuse with current intoxication is provided below. All of these codes are eligible for the payment adjustment.

- F14.120 Cocaine abuse with intoxication, uncomplicated
- F14.121 Cocaine abuse with intoxication with delirium
- F14.122 Cocaine abuse with intoxication with perceptual disturbance
- F14.129 Cocaine abuse with intoxication, unspecified

Next, ICD-10-CM contains separate, detailed codes by drug for specific drug-induced manifestations of mental disorder, such as drug-induced psychotic disorder with hallucinations. What was a single code in ICD-9-CM, 292.12 Drug-induced psychotic disorder with hallucinations, maps to 24 comparable codes in ICD-10-CM. We will include all of these more specific ICD-10-CM codes in the comorbidity category. We believe they are necessary for replication of the clinical intent of the comorbidity category so that all patients with a drug-induced psychotic disorder with hallucinations coded on the claim are eligible for the payment adjustment. Because the ICD-10-CM codes are not listed contiguously in the classification, they cannot be formatted as a range of codes and therefore must be listed as single codes in the comorbidity category definition.

The situation described above is similar for ICD-9-CM code 292.0 Drug withdrawal. ICD-10-CM contains separate, detailed codes by drug specifying that the patient is in withdrawal. We include all of these more specific ICD-10-CM codes in the comorbidity category. We believe they are necessary for replication of the clinical intent of the comorbidity category, so that all patients with a drug withdrawal code on the claim are eligible for the payment adjustment. Likewise, because the ICD-10-CM drug withdrawal codes are not listed contiguously in the classification, they cannot be formatted as a range of codes and so must be listed as single codes in the comorbidity category definition.

Conversion of the Poisoning Comorbidity Category

In ICD-10-CM, the Injury and Poisoning chapter has added an axis of

classification for every injury or poisoning diagnosis code, which specifies additional information about the current encounter. This creates three unique codes for each injury or poisoning diagnosis, marked by a different letter in the seventh character of the code:

1. The seventh character “A” in the code indicates that the poisoning is a current diagnosis in its “acute phase.”
2. The seventh character “D” in the code indicates that the poisoning is no longer in its “acute phase,” but that the patient is receiving aftercare for the earlier poisoning.
3. The seventh character “S” in the code indicates that the patient no longer requires care for any aspect of the poisoning itself, but that the patient is receiving care for a late effect of the poisoning.

The intent of the Poisoning comorbidity category is to include only those patients with a current diagnosis of poisoning. If the intent had been to include patients requiring only aftercare for an earlier, resolved case of poisoning, or for care associated with late effects of poisoning that occurred sometime in the past, the comorbidity category would have included ICD-9-CM aftercare codes or late effect codes, but it does not. Only acute poisoning codes from the ICD-9-CM classification are included. Therefore, the Poisoning comorbidity category will only include ICD-10-CM poisoning codes with a seventh character extension “A,” to indicate that the poisoning is documented as a current diagnosis.

In addition, ICD-10-CM poisoning codes specify the circumstances of the poisoning, whether documented as accidental, self-harm, assault, or undetermined, as shown in the heroin poisoning example below. We include all of these more specific ICD-10-CM codes in the comorbidity category for replication of the clinical intent of the comorbidity category so that all patients with a current diagnosis of poisoning coded on the claim would be eligible for the payment adjustment, as shown in the heroin poisoning example below:

- T40.1X1A Poisoning by heroin, accidental (unintentional), initial encounter
- T40.1X2A Poisoning by heroin, intentional self-harm, initial encounter
- T40.1X3A Poisoning by heroin, assault, initial encounter
- T40.1X4A Poisoning by heroin, undetermined, initial encounter

ICD-10-CM classifies poisoning by substance, alongside separate codes for adverse effect or underdosing of the

same substance. Because the poisoning codes are not listed contiguously in the classification, they cannot be formatted as a range of codes and therefore must be listed as single codes in the comorbidity category definition.

Proposed Elimination of Codes for Nonspecific Conditions Based on Side of the Body (Laterality)

We believe that highly descriptive coding provides the best and clearest way to document a patient’s condition and the appropriateness of the admission and treatment in an IPF. Therefore, whenever possible, we believe that the most specific code that describes a medical disease, condition, or injury should be used to document the patient’s diagnoses. Generally, “unspecified” codes are used when they most accurately reflect what is known about the patient’s condition at the time of that particular encounter (for example, there is a lack of information about a specific type of organism causing an illness). However, site of illness at the time of the medical encounter is an important determinant in assessing a patient’s principal or secondary diagnosis. For this reason, we believe that specific diagnosis codes that narrowly identify anatomical sites where disease, injury, or condition exist should be used when coding patients’ diagnoses whenever these codes are available. Furthermore, on the same note, we believe that one should also code to the highest specificity (use the full ICD-10-CM/PCS code).

In accordance with these principles, we remove site unspecified codes from the IPF PPS ICD-10-CM/PCS codes in instances in which more specific codes are available as the clinician should be able to identify a more specific diagnosis based on clinical assessment at the medical encounter. For example, the initial GEMS translation included non-specific codes such as ICD-10-CM code C44.111 “Basal Cell carcinoma of skin of unspecified eyelid, including canthus.” Under our rule:

- C44.111 Basal Cell Carcinoma of skin of unspecified eyelid will not be accepted.
- C44.112 Basal Cell Carcinoma of skin right eyelid will be accepted.
- C44.119 Basal Cell Carcinoma of skin left eyelid will be accepted.

We are removing these non-specific codes whenever a more specific diagnosis could be identified by the clinician performing the assessment. For example code C44.111, we are deleting this code because the clinician should be able to identify which eye had the basal cell carcinoma, and therefore will

report the condition using the code that specifies the right or left eye.

We are removing a total of 156 ICD-10-CM site unspecified codes involving

the following comorbidity categories:

Oncology-93 ICD-10-CM codes,
Gangrene-6 ICD-10-CM codes and
Severe Musculoskeletal and Connective

Tissue—57 ICD-10-CM codes. The site unspecified IPF PPS ICD-10-CM codes being removed are listed below in Tables 3 through 5.

TABLE 3—SITE UNSPECIFIED ICD-10-CM CODES TO BE REMOVED FROM THE ONCOLOGY TREATMENT COMORBIDITY CATEGORY

ICD-10-CM diagnosis	Code title
C40.00	Malignant neoplasm of scapula and long bones of unspecified upper limb.
C40.10	Malignant neoplasm of short bones of unspecified upper limb.
C40.20	Malignant neoplasm of long bones of unspecified lower limb.
C40.30	Malignant neoplasm of short bones of unspecified lower limb.
C40.80	Malignant neoplasm of overlapping sites of bone and articular cartilage of unspecified limb.
C40.90	Malignant neoplasm of unspecified bones and articular cartilage of unspecified limb.
C43.10	Malignant melanoma of unspecified eyelid, including canthus.
C43.20	Malignant melanoma of unspecified ear and external auricular canal.
C43.60	Malignant melanoma of unspecified upper limb, including shoulder.
C43.70	Malignant melanoma of unspecified lower limb, including hip.
C44.101	Unspecified malignant neoplasm of skin of unspecified eyelid, including canthus.
C44.111	Basal cell carcinoma of skin of unspecified eyelid, including canthus.
C44.121	Squamous cell carcinoma of skin of unspecified eyelid, including canthus.
C44.191	Other specified malignant neoplasm of skin of unspecified eyelid, including canthus.
C44.201	Unspecified malignant neoplasm of skin of unspecified ear and external auricular canal.
C44.211	Basal cell carcinoma of skin of unspecified ear and external auricular canal.
C44.221	Squamous cell carcinoma of skin of unspecified ear and external auricular canal.
C44.601	Unspecified malignant neoplasm of skin of unspecified upper limb, including shoulder.
C44.611	Basal cell carcinoma of skin of unspecified upper limb, including shoulder.
C44.621	Squamous cell carcinoma of skin of unspecified upper limb, including shoulder.
C44.691	Other specified malignant neoplasm of skin of unspecified upper limb, including shoulder.
C44.701	Unspecified malignant neoplasm of skin of unspecified lower limb, including hip.
C44.711	Basal cell carcinoma of skin of unspecified lower limb, including hip.
C44.721	Squamous cell carcinoma of skin of unspecified lower limb, including hip.
C44.791	Other specified malignant neoplasm of skin of unspecified lower limb, including hip.
C47.10	Malignant neoplasm of peripheral nerves of unspecified upper limb, including shoulder.
C47.20	Malignant neoplasm of peripheral nerves of unspecified lower limb, including hip.
C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder.
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip.
C4A.10	Merkel cell carcinoma of unspecified eyelid, including canthus.
C4A.20	Merkel cell carcinoma of unspecified ear and external auricular canal.
C4A.60	Merkel cell carcinoma of unspecified upper limb, including shoulder.
C4A.70	Merkel cell carcinoma of unspecified lower limb, including hip.
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast.
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast.
C50.119	Malignant neoplasm of central portion of unspecified female breast.
C50.129	Malignant neoplasm of central portion of unspecified male breast.
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast.
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast.
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast.
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast.
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast.
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast.
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast.
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast.
C50.619	Malignant neoplasm of axillary tail of unspecified female breast.
C50.629	Malignant neoplasm of axillary tail of unspecified male breast.
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast.
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast.
C50.919	Malignant neoplasm of unspecified site of unspecified female breast.
C50.929	Malignant neoplasm of unspecified site of unspecified male breast.
C69.00	Malignant neoplasm of unspecified conjunctiva.
C69.10	Malignant neoplasm of unspecified cornea.
C69.50	Malignant neoplasm of unspecified lacrimal gland and duct.
C69.60	Malignant neoplasm of unspecified orbit.
C69.80	Malignant neoplasm of overlapping sites of unspecified eye and adnexa.
C69.90	Malignant neoplasm of unspecified site of unspecified eye.
C76.40	Malignant neoplasm of unspecified upper limb.
C76.50	Malignant neoplasm of unspecified lower limb.
D03.10	Melanoma in situ of unspecified eyelid, including canthus.
D03.20	Melanoma in situ of unspecified ear and external auricular canal.
D03.60	Melanoma in situ of unspecified upper limb, including shoulder.
D03.70	Melanoma in situ of unspecified lower limb, including hip.
D04.10	Carcinoma in situ of skin of unspecified eyelid, including canthus.
D04.20	Carcinoma in situ of skin of unspecified ear and external auricular canal.

TABLE 3—SITE UNSPECIFIED ICD-10-CM CODES TO BE REMOVED FROM THE ONCOLOGY TREATMENT COMORBIDITY CATEGORY—Continued

ICD-10-CM diagnosis	Code title
D04.60	Carcinoma in situ of skin of unspecified upper limb, including shoulder.
D04.70	Carcinoma in situ of skin of unspecified lower limb, including hip.
D05.00	Lobular carcinoma in situ of unspecified breast.
D05.10	Intraductal carcinoma in situ of unspecified breast.
D05.80	Other specified type of carcinoma in situ of unspecified breast.
D05.90	Unspecified type of carcinoma in situ of unspecified breast.
D09.20	Carcinoma in situ of unspecified eye.
D16.00	Benign neoplasm of scapula and long bones of unspecified upper limb.
D16.10	Benign neoplasm of short bones of unspecified upper limb.
D16.20	Benign neoplasm of long bones of unspecified lower limb.
D16.30	Benign neoplasm of short bones of unspecified lower limb.
D17.20	Benign lipomatous neoplasm of skin and subcutaneous tissue of unspecified limb.
D21.10	Benign neoplasm of connective and other soft tissue of unspecified upper limb, including shoulder.
D21.20	Benign neoplasm of connective and other soft tissue of unspecified lower limb, including hip.
D22.10	Melanocytic nevi of unspecified eyelid, including canthus.
D22.20	Melanocytic nevi of unspecified ear and external auricular canal.
D22.60	Melanocytic nevi of unspecified upper limb, including shoulder.
D22.70	Melanocytic nevi of unspecified lower limb, including hip.
D23.10	Other benign neoplasm of skin of unspecified eyelid, including canthus.
D23.20	Other benign neoplasm of skin of unspecified ear and external auricular canal.
D23.60	Other benign neoplasm of skin of unspecified upper limb, including shoulder.
D23.70	Other benign neoplasm of skin of unspecified lower limb, including hip.
D24.9	Benign neoplasm of unspecified breast.
D31.00	Benign neoplasm of unspecified conjunctiva.
D31.50	Benign neoplasm of unspecified lacrimal gland and duct.
D31.60	Benign neoplasm of unspecified site of unspecified orbit.
D31.90	Benign neoplasm of unspecified part of unspecified eye.
D48.60	Neoplasm of uncertain behavior of unspecified breast.

TABLE 4—SITE UNSPECIFIED ICD-10-CM CODES TO BE REMOVED FROM THE GANGRENE COMORBIDITY CATEGORY

ICD10	ICD10 description
I70269	Atherosclerosis of native arteries of extremities with gangrene, unspecified extremity.
I70369	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with gangrene, unspecified extremity.
I70469	Atherosclerosis of autologous vein bypass graft(s) of the extremities with gangrene, unspecified extremity.
I70569	Atherosclerosis of nonautologous biological bypass graft(s) of the extremities with gangrene, unspecified extremity.
I70669	Atherosclerosis of nonbiological bypass graft(s) of the extremities with gangrene, unspecified extremity.
I70769	Atherosclerosis of other type of bypass graft(s) of the extremities with gangrene, unspecified extremity.

TABLE 5—SITE UNSPECIFIED ICD-10-CM CODES TO BE REMOVED FROM THE SEVERE MUSCULOSKELETAL AND CONNECTIVE TISSUE DISEASES CATEGORY

ICD10	ICD10 description
M8600	Acute hematogenous osteomyelitis, unspecified site.
M86019	Acute hematogenous osteomyelitis, unspecified shoulder.
M86029	Acute hematogenous osteomyelitis, unspecified humerus.
M86039	Acute hematogenous osteomyelitis, unspecified radius and ulna.
M86049	Acute hematogenous osteomyelitis, unspecified hand.
M86059	Acute hematogenous osteomyelitis, unspecified femur.
M86069	Acute hematogenous osteomyelitis, unspecified tibia and fibula.
M86079	Acute hematogenous osteomyelitis, unspecified ankle and foot.
M8610	Other acute osteomyelitis, unspecified site.
M86119	Other acute osteomyelitis, unspecified shoulder.
M86129	Other acute osteomyelitis, unspecified humerus.
M86139	Other acute osteomyelitis, unspecified radius and ulna.
M86149	Other acute osteomyelitis, unspecified hand.
M86159	Other acute osteomyelitis, unspecified femur.
M86169	Other acute osteomyelitis, unspecified tibia and fibula.
M86179	Other acute osteomyelitis, unspecified ankle and foot.
M8620	Subacute osteomyelitis, unspecified site.
M86219	Subacute osteomyelitis, unspecified shoulder.
M86229	Subacute osteomyelitis, unspecified humerus.
M86239	Subacute osteomyelitis, unspecified radius and ulna.
M86249	Subacute osteomyelitis, unspecified hand.
M86259	Subacute osteomyelitis, unspecified femur.
M86269	Subacute osteomyelitis, unspecified tibia and fibula.

TABLE 5—SITE UNSPECIFIED ICD-10-CM CODES TO BE REMOVED FROM THE SEVERE MUSCULOSKELETAL AND CONNECTIVE TISSUE DISEASES CATEGORY—Continued

ICD10	ICD10 description
M86279	Subacute osteomyelitis, unspecified ankle and foot.
M8630	Chronic multifocal osteomyelitis, unspecified site.
M86319	Chronic multifocal osteomyelitis, unspecified shoulder.
M86329	Chronic multifocal osteomyelitis, unspecified humerus.
M86339	Chronic multifocal osteomyelitis, unspecified radius and ulna.
M86349	Chronic multifocal osteomyelitis, unspecified hand.
M86359	Chronic multifocal osteomyelitis, unspecified femur.
M86369	Chronic multifocal osteomyelitis, unspecified tibia and fibula.
M86379	Chronic multifocal osteomyelitis, unspecified ankle and foot.
M8640	Chronic osteomyelitis with draining sinus, unspecified site.
M86419	Chronic osteomyelitis with draining sinus, unspecified shoulder.
M86429	Chronic osteomyelitis with draining sinus, unspecified humerus.
M86439	Chronic osteomyelitis with draining sinus, unspecified forearm.
M86449	Chronic osteomyelitis with draining sinus, unspecified hand.
M86459	Chronic osteomyelitis with draining sinus, unspecified femur.
M86469	Chronic osteomyelitis with draining sinus, unspecified lower leg.
M86479	Chronic osteomyelitis with draining sinus, unspecified ankle and foot.
M8650	Other chronic hematogenous osteomyelitis, unspecified site.
M86519	Other chronic hematogenous osteomyelitis, unspecified shoulder.
M86529	Other chronic hematogenous osteomyelitis, unspecified humerus.
M86539	Other chronic hematogenous osteomyelitis, unspecified forearm.
M86549	Other chronic hematogenous osteomyelitis, unspecified hand.
M86559	Other chronic hematogenous osteomyelitis, unspecified femur.
M86569	Other chronic hematogenous osteomyelitis, unspecified lower leg.
M86579	Other chronic hematogenous osteomyelitis, unspecified ankle and foot.
M8660	Other chronic osteomyelitis, unspecified site.
M86619	Other chronic osteomyelitis, unspecified shoulder.
M86629	Other chronic osteomyelitis, unspecified upper arm.
M86639	Other chronic osteomyelitis, unspecified forearm.
M86649	Other chronic osteomyelitis, unspecified hand.
M86659	Other chronic osteomyelitis, unspecified thigh.
M86669	Other chronic osteomyelitis, unspecified tibia and fibula.
M86679	Other chronic osteomyelitis, unspecified ankle and foot.
M868x9	Other osteomyelitis, unspecified sites.

There are some site unspecified ICD-10-CM codes that we are not removing. In the case where the site unspecified code is the only available ICD-10-CM code, that is when a laterality code (site

specific code) is not available, the site unspecified code will not be removed and it would be appropriate to submit that code.

Currently, IPFs are receiving the comorbidity adjustment using the ICD-9-CM diagnosis codes for the comorbidity categories shown in Table 6 below.

TABLE 6—FY 2014 CURRENT DIAGNOSIS CODES AND ADJUSTMENT FACTORS FOR COMORBIDITY CATEGORIES

Description of comorbidity	ICD-9-CM diagnoses codes	Adjustment factor
Developmental Disabilities	317, 3180, 3181, 3182, and 319	1.04
Coagulation Factor Deficits	2860 through 2864	1.13
Tracheostomy	51900 through 51909 and V440	1.06
Renal Failure, Acute	5845 through 5849, 63630, 63631, 63632, 63730, 63731, 63732, 6383, 6393, 66932, 66934, 9585.	1.11
Renal Failure, Chronic	40301, 40311, 40391, 40402, 40412, 40413, 40492, 40493, 5853, 5854, 5855, 5856, 5859, 586, V4511, V4512, V560, V561, and V562.	1.11
Oncology Treatment	1400 through 2399 with a radiation therapy code 92.21–92.29 or chemotherapy code 99.25.	1.07
Uncontrolled Diabetes-Mellitus with or without complications.	25002, 25003, 25012, 25013, 25022, 25023, 25032, 25033, 25042, 25043, 25052, 25053, 25062, 25063, 25072, 25073, 25082, 25083, 25092, and 25093.	1.05
Severe Protein Calorie Malnutrition	260 through 262	1.13
Eating and Conduct Disorders	3071, 30750, 31203, 31233, and 31234	1.12
Infectious Disease	01000 through 04110, 042, 04500 through 05319, 05440 through 05449, 0550 through 0770, 0782 through 07889, and 07950 through 07959.	1.07
Drug and/or Alcohol Induced Mental Disorders ..	2910, 2920, 29212, 2922, 30300, and 30400	1.03
Cardiac Conditions	3910, 3911, 3912, 40201, 40403, 4160, 4210, 4211, and 4219	1.11
Gangrene	44024 and 7854	1.10
Chronic Obstructive Pulmonary Disease	49121, 4941, 5100, 51883, 51884, V4611, V4612, V4613 and V4614	1.12
Artificial Openings—Digestive and Urinary	56960 through 56969, 9975, and V441 through V446	1.08

TABLE 6—FY 2014 CURRENT DIAGNOSIS CODES AND ADJUSTMENT FACTORS FOR COMORBIDITY CATEGORIES—
Continued

Description of comorbidity	ICD-9-CM diagnoses codes	Adjustment factor
Severe Musculoskeletal and Connective Tissue Disease.	6960, 7100, 73000 through 73009, 73010 through 73019, and 73020 through 73029.	1.09
Poisoning	96500 through 96509, 9654, 9670 through 9699, 9770, 9800 through 9809, 9830 through 9839, 986, 9890 through 9897.	1.11

Final Rule Action: For FY 2015, we are applying the 17 comorbidity categories for which we provide an adjustment as shown in Table 6 above.

Also, the ICD-10-CM/PCS codes and adjustment factors shown in Table 7 below, as well as, the removal of 153 site unspecified ICD-10-CM codes in

Tables 3 through 5 above will go into effect October 1, 2015.

TABLE 7—FY 2015 DIAGNOSIS CODES AND ADJUSTMENT FACTORS FOR COMORBIDITY CATEGORIES

Description of comorbidity	ICD-10-CM diagnoses codes	Adjustment factor
Developmental Disabilities	F70 through F79	1.04
Coagulation Factor Deficits	D66 through D682	1.13
Tracheostomy	J9500 through J9509, and Z930	1.06
Renal Failure, Acute	N170 through N179, O0482, O0732, O084 O904, and T795XXA	1.11
Renal Failure, Chronic	I120, I1311 through I132, N183 through N19, Z4901 through Z4931, Z9115, and Z992.	1.11
Oncology Treatment	C000 through C4002, C4011, C4012 C4021, C4022, C4031, C4032, C4081, C4082, C4091 through C430, C4311, C4312, C4321, C4322, C4361, C4362, C4371, C4372 through C4409, C44102, C44109, C44112, C44119, C44122, C44129, C44191, C44192, C44202, C44209, C44212, C44219, C44222, C44229 through C44599, C44602, C44609, C44612, C44619, C44622, C44629, C44692, C44699, C44702, C44709, C44712, C44719, C44722, C44729, C44792, C44799 through C470, C4711, C4712, C4721, C4722 through C490, C4911, C4912, C4921, C4922 through C4A0, C4A11, C4A12, C4A21, C4A22 through C4A59, C4A61, C4A62, C4A71, C4A72 through C50012, C50021, C50022, C50111, C50112, C50121, C50122, C50211, C50212, C50221, C50222, C50311, C50312, C50321, C50322, C50411, C50412, C50421, C50422, C50511, C50512, C50521, C50522, C50611, C50612, C50621, C50622, C50811, C50812, C50821, C50822, C50911, C50912, C50921, C50922, C510 through C689, C6901, C6902, C6911, C6912 through C6942, C6951, C6952, C6961, C6962, C6981, C6982, C6991, C6992 through C763, C7641, C7642, C7651, C7652 through C866, C882 through C964, C96A, C96Z, C969 through D030, D0311, D0312, D0321, D0322 through D0359, D0361, D0362, D0371, D0372 through D040, D0411, D0412, D0421, D0422 through D045, D0461, D0462, D0471, D0472 through D049, D0501, D0502, D0511, D0512, D0581, D0582, D0591, D0592 through D0919, D0921 through D159, D1601, D1602, D1611, D1612, D1621, D1622, D1631, D1632 through D171, D1721 through D210, D2111, D2112, D2121, D2122 through D220, D2211, D2212, D2221, D2222, D225 through D2261, D2262, D2271, D2272 through D230, D2311, D2312, D2321, D2322 through D235, D2361, D2362, D2371, D2372 through D242, D250 through D309, D3101 through D3142, D3151, D3152, D3161, D3162, D3191, D3192 through D485, D4861 through D471, D473, D47Z1 through D47Z9, D479 through D499, K317, K635, Q8500, and Q8501 through Q8509 with a radiation therapy code from ICD-10-PCS tables 08H through 0YH with a sixth character device value 1 Radioactive Element, ICD-10-PCS table CW7, ICD-10-PCS tables D00 through DW0, ICD-10-PCS tables D01 through DW1, tables D0Y through DWY, or a chemotherapy code from ICD-10-PCS table 3E0 with a sixth character substance value 0 Antineoplastic and a seventh character qualifier 5 Other Antineoplastic.	1.07
Uncontrolled Diabetes-Mellitus with or without complications.	E1065 and E1165	1.05
Severe Protein Calorie Malnutrition	E40 through E43	1.13
Eating and Conduct Disorders	F5000 through F5002, F509, F631, F6381, and F911	1.12

TABLE 7—FY 2015 DIAGNOSIS CODES AND ADJUSTMENT FACTORS FOR COMORBIDITY CATEGORIES—Continued

Description of comorbidity	ICD-10—CM diagnoses codes	Adjustment factor
Infectious Disease	A150 through A269, A280 through A329, A35 through A439, A46 through A480, A482 through A488, A491, A70 through A740, A7489, A800 through A99, B0050 through B0059, B010 through B0229, B03 through B069, B08010 through B0809, B0820 through B2799, B330 through B333, B338, B341, B471 through B479, B950 through B955, B958, B9730 through B9739, G032, I673, J020, J0300, J0301, J202, K9081, L081, L444, M60009, and R1111.	1.07
Drug and/or Alcohol Induced Mental Disorders	Alcohol dependence with intoxication and/or withdrawal F10121, F10220 through F10229, F10231, and F10921 Drug withdrawal F1193, F1123, F13230 through F13239, F13930 through F13939, F1423, F1523, F1593, F17203, F17213, F17223, F17293, F19230 through F19239, and F19930 through F19939. Drug-induced psychotic disorder with hallucinations F11251, F11151, F11951, F12151, F12251, F13151, F12951, F13251, F13951, F14151, F14251, F14951, F15151, F15251, F15951, F16151, F16251, F16951, F18151, F18251, F18951, F19151, F19251, and F19951. Drug intoxication F11220 through F11229, F11920 through F11929, F12120 through F12129, F12220 through F12229, F12920 through F12929, F13120 through F13129, F13220 through F13229, F13920 through F13929, F14120 through F14129, F14220 through F14229, F14920 through F14929, F15120 through F15129, F15220 through F15229, F15920 through F15929, F16120 through F16129, F16220 through F16229, F16920 through F16929, F18120 through F18129, F18220 through F18229, F18920 through F18929, F19120 through F19129, F19220 through F19229, F19230 through F19239, and F19920 through F19929. Opioid dependence not listed above F1120, F1124, F11250, F11259, F11281 through F11288, F1129	1.03
Cardiac Conditions	I010 through I012, I110, I270, I330 through I339, and I39	1.11
Gangrene	E0852, E0952, E1052, E1152, E1352, I70261 through I70268, I70361 through I70368, I70461 through I70468, I70561 through I70568, I70661 through I70668, I70761 through I70768, I7301, and I96.	1.10
Chronic Obstructive Pulmonary Disease	J441, J470 through J471, J860, J95850, J9610 through J9622, and Z9911 through Z9912.	1.12
Artificial Openings—Digestive and Urinary	K9400 through K9419, N990, N99520 through N99538, N9981, N9989, and Z931 through Z936.	1.08
Severe Musculoskeletal and Connective Tissue Diseases.	L4050 through L4059, M320 through M329, M4620 through M4628, M86011, M86012, M86021, M86022, M86031, M86032, M86041, M86042, M86051, M86052, M86061, M86062, M86071, M86072, M8608, M8609, M86111, M86112, M86121, M86122, M86131, M86132, M86141, M86142, M86151, M86152, M86161, M86162, M86171, M86172, M8618, M8619, M86211, M86212, M86221, M86222, M86231, M86232, M86241, M86242, M86251, M86252, M86261, M86262, M86271, M86272, M8628, M8629, M86311, M86312, M86321, M86322, M86331, M86332, M86341, M86342, M86351, M86352, M86361, M86362, M86371, M86372, M8638, M8639, M86411, M86412, M86421, M86422, M86431, M86432, M86441, M86442, M86451, M86452, M86461, M86462, M86471, M86472, M8648, M8649, M86511, M86512, M86521, M86522, M86531, M86532, M86541, M86542, M86551, M86552, M86561, M86562, M86571, M86572, M8658, M8659, M86611, M86612, M86621, M86622, M86631, M86632, M86641, M86642, M86651, M86652, M86661, M86662, M86671, M86672, M8668, M8669, M868X0, M868X1, M868X2, M868X3, M868X4, M868X5, M868X6, M868X7, M868X8, and M869.	1.09
Poisoning	Note: Only includes the codes below with seventh character A specifying initial encounter.	1.11

TABLE 7—FY 2015 DIAGNOSIS CODES AND ADJUSTMENT FACTORS FOR COMORBIDITY CATEGORIES—Continued

Description of comorbidity	ICD-10-CM diagnoses codes	Adjustment factor
	T391X1 through T391X4, T400X1 through T400X4, T401X1 through T401X4, T402X1 through T402X4, T403X1 through T403X4, T404X1 through T404X4, T40601 through T40604, T40691 through T40694, T407X1 through T407X4, T408X1 through T408X4, T40901 through T40904, T40991 through T40994, T410X1 through T410X4, T411X1 through T411X4, T41201 through T41204, T41291 through T41294, T413X1 through T413X4, T4141X through T4144X, T423X1 through T423X4, T424X1 through T424X4, T426X1 through T426X4, T4271X through T4274X, T428X1 through T428X4, T43011 through T43014, T43021 through T43024, T431X1 through T431X4, T43201 through T43204, T43211 through T43214, T43221 through T43224, T43291 through T43294, T433X1 through T433X4, T434X1 through T434X4, T43501 through T43504, T43591 through T43594, T43601 through T43604, T43611 through T43614, T43621 through T43624, T43631 through T43634, T43691 through T43694, T438X1 through T438X4, T4391X through T4394X, T505X1 through T505X4, T510X1 through T5194X, T510X1 through T510X4, T5391X through T5394X, T540X1 through T5494X, T550X1 through T551X4, T560X1 through T560X4, T571X1 through T571X4, T5801X through T5804X, T5811X through T5814X, T582X1 through T582X4, T588X1 through T588X4, T5891X through T5894X, T600X1 through T600X4, T601X1 through T601X4, T602X1 through T602X4, T6041X through T6094X, T63001 through T6394X, T6401X through T6484X, T650X1 through T650X4, T651X1 through T651X4.	

3. Patient Age Adjustments

As explained in the November 2004 IPF PPS final rule (69 FR 66922), we analyzed the impact of age on per diem cost by examining the age variable (that is, the range of ages) for payment adjustments.

In general, we found that the cost per day increases with age. The older age groups are more costly than the under 45 age group, the differences in per diem cost increase for each successive age group, and the differences are statistically significant.

For FY 2015, we will continue to use the patient age adjustments currently in effect as shown in Table 8 below.

TABLE 8—AGE GROUPINGS AND ADJUSTMENT FACTORS

Age	Adjustment factor
Under 45	1.00
45 and under 50	1.01
50 and under 55	1.02
55 and under 60	1.04
60 and under 65	1.07
65 and under 70	1.10
70 and under 75	1.13
75 and under 80	1.15
80 and over	1.17

Final Rule Action: We received no comments on the FY 2015 IPF PPS proposed rule concerning the age adjustment. We are adopting the age adjustments currently in effect and as shown in Table 8 above for FY 2015.

4. Variable Per Diem Adjustments

We explained in the November 2004 IPF PPS final rule (69 FR 66946) that the regression analysis indicated that per diem cost declines as the LOS increases. The variable per diem adjustments to the Federal per diem base rate account for ancillary and administrative costs that occur disproportionately in the first days after admission to an IPF.

We used a regression analysis to estimate the average differences in per diem cost among stays of different lengths. As a result of this analysis, we established variable per diem adjustments that begin on day 1 and decline gradually until day 21 of a patient's stay. For day 22 and thereafter, the variable per diem adjustment remains the same each day for the remainder of the stay. However, the adjustment applied to day 1 depends upon whether the IPF has a qualifying emergency department (ED). If an IPF has a qualifying ED, it receives a 1.31 adjustment factor for day 1 of each stay. If an IPF does not have a qualifying ED, it receives a 1.19 adjustment factor for day 1 of the stay. The ED adjustment is explained in more detail in section VII.C.5 of this final rule.

For FY 2015, we will continue to use the variable per diem adjustment factors currently in effect as shown in Table 9 below. A complete discussion of the variable per diem adjustments appears in the November 2004 IPF PPS final rule (69 FR 66946).

TABLE 9—VARIABLE PER DIEM ADJUSTMENTS

Day-of-stay	Adjustment factor
Day 1- IPF Without a Qualifying ED	1.19
Day 1- IPF With a Qualifying ED	1.31
Day 2	1.12
Day 3	1.08
Day 4	1.05
Day 5	1.04
Day 6	1.02
Day 7	1.01
Day 8	1.01
Day 9	1.00
Day 10	1.00
Day 11	0.99
Day 12	0.99
Day 13	0.99
Day 14	0.99
Day 15	0.98
Day 16	0.97
Day 17	0.97
Day 18	0.96
Day 19	0.95
Day 20	0.95
Day 21	0.95
After Day 21	0.92

Final Rule Action: In response to the FY 2015 IPF PPS proposed rule, we received no public comments concerning the variable per diem adjustment. We are adopting the variable per diem adjustments currently in effect and as shown in Table 9 above for FY 2015.

C. Facility-Level Adjustments

The IPF PPS includes facility-level adjustments for the wage index, IPFs located in rural areas, teaching IPFs, cost of living adjustments for IPFs located in Alaska and Hawaii, and IPFs with a qualifying ED.

1. Wage Index Adjustment

a. Background

As discussed in the May 2006 IPF PPS final rule (71 FR 27061) and in the May 2008 (73 FR 25719) and May 2009 IPF PPS notices (74 FR 20373), in order to provide an adjustment for geographic wage levels, the labor-related portion of an IPF's payment is adjusted using an appropriate wage index. Currently, an IPF's geographic wage index value is determined based on the actual location of the IPF in an urban or rural area as defined in § 412.64(b)(1)(ii)(A) and (C).

b. Wage Index for FY 2015

Since the inception of the IPF PPS, we have used the pre-reclassified, pre-floor hospital wage index in developing a wage index to be applied to IPFs because there is not an IPF-specific wage index available and we believe that IPFs generally compete in the same labor market as acute care hospitals so the pre-reclassified, pre-floor inpatient acute care hospital wage index should be reflective of labor costs of IPFs. As discussed in the May 2006 IPF PPS final rule for FY 2007 (71 FR 27061 through 27067), under the IPF PPS, the wage index is calculated using the IPPS wage index for the labor market area in which the IPF is located, without taking into account geographic reclassifications, floors, and other adjustments made to the wage index under the IPPS. For a complete description of these IPPS wage index adjustments, please see the CY 2013 IPPS/LTCH PPS final rule (77 FR 53365 through 53374). We will continue that practice for FY 2015.

We apply the wage index adjustment to the labor-related portion of the Federal rate, which is currently estimated to be 69.294 percent. This percentage reflects the labor-related relative importance of the FY 2008-based RPL market basket for FY 2015 (see section V.C. of this final rule).

Changes to the wage index are made in a budget-neutral manner so that updates do not increase expenditures. For FY 2015, we are applying the most recent hospital wage index (that is, the FY 2014 pre-floor, pre-reclassified hospital wage index which is the most appropriate index as it best reflects the variation in local labor costs of IPFs in the various geographic areas) using the most recent hospital wage data (that is,

data from hospital cost reports for the cost reporting period beginning during FY 2010), and applying an adjustment in accordance with our budget-neutrality policy. This policy requires us to estimate the total amount of IPF PPS payments for FY 2014 using the labor-related share and the wage indices from FY 2014 divided by the total estimated IPF PPS payments for FY 2015 using the labor-related share and wage indices from FY 2015. The estimated payments are based on FY 2013 IPF claims, inflated to the appropriate FY. This quotient is the wage index budget-neutrality factor, and it is applied in the update of the Federal per diem base rate for FY 2015 in addition to the market basket described in section VI.B. of this final rule. The wage index budget-neutrality factor for FY 2015 is 1.0002. The wage index applicable for FY 2015 appears in Table 1 and Table 2 in Addendum B of this final rule.

In the May 2006 IPF PPS final rule for FY 2007 (71 FR 27061–27067), we adopted the changes discussed in the Office of Management and Budget (OMB) Bulletin No. 03–04 (June 6, 2003), which announced revised definitions for Metropolitan Statistical Areas (MSAs), and the creation of Micropolitan Statistical Areas and Combined Statistical Areas. In adopting the OMB Core-Based Statistical Area (CBSA) geographic designations, we did not provide a separate transition for the CBSA-based wage index since the IPF PPS was already in a transition period from TEFRA payments to PPS payments.

As was the case in FY 2014, for FY 2015, we will continue to use the CBSA geographic designations. The updated FY 2015 CBSA-based wage index values are presented in Tables 1 and 2 in Addendum B of this final rule. A complete discussion of the CBSA labor market definitions appears in the May 2006 IPF PPS final rule (71 FR 27061 through 27067).

In keeping with established IPF PPS wage index policy, we are using the FY 2014 pre-floor, pre-reclassified hospital wage index (which is based on data collected from hospital cost reports submitted by hospitals for cost reporting periods beginning during FY 2010) to adjust IPF PPS payments beginning October 1, 2014.

c. OMB Bulletins

OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. In the May 2008 IPF PPS notice, we incorporated the CBSA nomenclature changes published in the most recent OMB

bulletin that applies to the hospital wage index used to determine the current IPF PPS wage index and stated that we expect to continue to do the same for all the OMB CBSA nomenclature changes in future IPF PPS rules and notices, as necessary (73 FR 25721). The OMB bulletins may be accessed online at <http://www.whitehouse.gov/omb/bulletins/index.html>.

In accordance with our established methodology, we have historically adopted any CBSA changes that are published in the OMB bulletin that corresponds with the hospital wage index used to determine the IPF PPS wage index. For FY 2015, we use the FY 2014 pre-floor, pre-reclassified hospital wage index to adjust the IPF PPS payments. On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which establishes revised delineations of statistical areas based on OMB standards published in the **Federal Register** on June 28, 2010 and 2010 Census Bureau data. Because the FY 2014 pre-floor, pre-reclassified hospital wage index was finalized prior to the issuance of this Bulletin, the FY 2014 pre-floor, pre-reclassified hospital wage index does not reflect OMB's new area delineations based on the 2010 Census and, thus, the FY 2015 IPF PPS wage index will not reflect the OMB changes.

CMS will use the hospital wage index based on the OMB Bulletin in the FY 2015 IPPS/LTCH PPS final rule. Therefore, the OMB Bulletin changes are reflected in the FY 2015 hospital wage index. Because we base the IPF PPS wage index on the hospital wage index from the prior year, we anticipate that the OMB Bulletin changes will be reflected in the FY 2016 IPPS wage index.

Final Rule Action: In response to the FY 2015 IPF PPS proposed rule, we received no comments concerning the wage adjustment. We are adopting the FY 2014 pre-floor, pre-reclassified hospital wage index for FY 2015.

2. Adjustment for Rural Location

In the November 2004 IPF PPS final rule, we provided a 17 percent payment adjustment for IPFs located in a rural area. This adjustment was based on the regression analysis, which indicated that the per diem cost of rural facilities was 17 percent higher than that of urban facilities after accounting for the influence of the other variables included in the regression. For FY 2015, we are applying a 17 percent payment adjustment for IPFs located in a rural area as defined at § 412.64(b)(1)(ii)(C). A complete discussion of the adjustment for rural locations appears in the

November 2004 IPF PPS final rule (69 FR 66954).

Final Rule Action: In response to the FY 2015 IPF PPS proposed rule, we received no comments concerning the rural adjustment. We are adopting the rural adjustments currently in effect for FY 2015.

3. Teaching Adjustment

In the November 2004 IPF PPS final rule, we implemented regulations at § 412.424(d)(1)(iii) to establish a facility-level adjustment for IPFs that are, or are part of, teaching hospitals. The teaching adjustment accounts for the higher indirect operating costs experienced by hospitals that participate in graduate medical education (GME) programs. The payment adjustments are made based on the ratio of the number of full-time equivalent (FTE) interns and residents training in the IPF and the IPF's average daily census.

Medicare makes direct GME payments (for direct costs such as resident and teaching physician salaries, and other direct teaching costs) to all teaching hospitals including those paid under a PPS, and those paid under the TEFRA rate-of-increase limits. These direct GME payments are made separately from payments for hospital operating costs and are not part of the IPF PPS. The direct GME payments do not address the estimated higher indirect operating costs teaching hospitals may face.

The results of the regression analysis of FY 2002 IPF data established the basis for the payment adjustments included in the November 2004 IPF PPS final rule. The results showed that the indirect teaching cost variable is significant in explaining the higher costs of IPFs that have teaching programs. We calculated the teaching adjustment based on the IPF's "teaching variable," which is one plus the ratio of the number of FTE residents training in the IPF (subject to limitations described below) to the IPF's average daily census (ADC).

We established the teaching adjustment in a manner that limited the incentives for IPFs to add FTE residents for the purpose of increasing their teaching adjustment. We imposed a cap on the number of FTE residents that may be counted for purposes of calculating the teaching adjustment. The cap limits the number of FTE residents that teaching IPFs may count for the purpose of calculating the IPF PPS teaching adjustment, not the number of residents teaching institutions can hire or train. We calculated the number of FTE residents that trained in the IPF during a "base year" and used that FTE

resident number as the cap. An IPF's FTE resident cap is ultimately determined based on the final settlement of the IPF's most recent cost report filed before November 15, 2004 (that is, the publication date of the IPF PPS final rule).

In the regression analysis, the logarithm of the teaching variable had a coefficient value of 0.5150. We converted this cost effect to a teaching payment adjustment by treating the regression coefficient as an exponent and raising the teaching variable to a power equal to the coefficient value. We note that the coefficient value of 0.5150 was based on the regression analysis holding all other components of the payment system constant. A complete discussion of how the teaching adjustment was calculated appears in the November 2004 IPF PPS final rule (69 FR 66954 through 66957) and the May 2008 IPF PPS notice (73 FR 25721).

Final Rule Action: As with other adjustment factors derived through the regression analysis, we do not plan to rerun the regression analysis until we analyze IPF PPS data. Therefore, in this final rule, for FY 2015, we are retaining the coefficient value of 0.5150 for the teaching adjustment to the Federal per diem base rate.

a. FTE Intern and Resident Cap Adjustment

CMS had been asked by the IPF industry to reconsider the original IPF teaching policy and permit a temporary increase in the FTE resident cap when an IPF increases the number of FTE residents it trains due to the acceptance of displaced residents (residents that are training in an IPF or a program before the IPF or program closed) when another IPF closes or closes its medical residency training program.

To help us assess how many IPFs had been, or were expected to be adversely affected by their inability to adjust their caps under § 412.424(d)(1)(iii) and under these situations, we specifically requested public comment from IPFs in the May 1, 2009 IPF PPS notice (74 FR 20376 through 20377). A summary of the comments and our responses can be reviewed in the April 30, 2010 IPF PPS notice (75 FR 23106 through 23117). All of the commenters recommended that CMS modify the IPF PPS teaching adjustment policy, supporting a policy change that would permit the IPF PPS residency cap to be temporarily adjusted when that IPF trains displaced residents due to closure of an IPF or closure of an IPF's medical residency training program(s). The commenters recommended a temporary resident cap adjustment policy similar to the policies

applied in similar contexts for acute care hospitals.

We agreed with the commenters therefore, in the May 6, 2011 IPF PPS final rule (76 FR 26455), we adopted the temporary resident cap adjustment policies described below, similar to the temporary adjustments to the FTE cap used for acute care hospitals.

b. Temporary Adjustment to the FTE Cap To Reflect Residents Added Due to Hospital Closure

In the May 6, 2011 IPF PPS final rule (76 FR 26455), we added a new § 412.424(d)(1)(iii)(F)(1) to allow a temporary adjustment to an IPF's FTE cap to reflect residents added because of another IPF's closure on or after July 1, 2011, to be effective for cost reporting periods beginning on or after July 1, 2011. For purposes of this policy, we adopted the IPPS definition of "closure of a hospital" in 42 CFR 413.79(h) to mean the IPF terminates its Medicare provider agreement as specified in 42 CFR 489.52. The regulations permit an adjustment to an IPF's FTE cap if the IPF meets the following criteria: (1) The IPF is training displaced residents from another IPF that closed on or after July 1, 2011; and (2) no later than 60 days after the hospital first begins training the displaced residents, the IPF that is training the displaced residents from the closed IPF submits a request for a temporary adjustment to its FTE cap to its Medicare Administrative Contractor (MAC), and documents that the IPF is eligible for this temporary adjustment to its FTE cap by identifying the residents who have come from the closed IPF and have caused the requesting IPF to exceed its cap, (or the IPF may already be over its cap) and specifies the length of time that the adjustment is needed.

After the displaced residents leave the IPF's training program or complete their residency program, the IPF's cap would revert to its original level. Further, the total amount of temporary cap adjustments that can be distributed to all receiving hospitals cannot exceed the cap amount of the IPF that closed.

c. Temporary Adjustment to FTE Cap To Reflect Residents Affected by Residency Program Closure

In the May 6, 2011 final rule (76 FR 26455), we added a new § 412.424(d)(1)(iii)(F)(2) providing that if an IPF that ceases training residents in a residency training program(s) agrees to temporarily reduce its FTE cap, we would allow another IPF to receive a temporary adjustment to its FTE cap to reflect residents added because of the closure of another IPF's residency training program. For purposes of this

policy on closed residency programs, we apply the IPPS definition of “closure of a hospital residency training program” to mean that the hospital ceases to offer training for residents in a particular approved medical residency training program as specified in § 413.79(h). The methodology for adjusting the caps for the “receiving IPF” and the “IPF that closed its program” is described below.

i. Receiving IPF

The regulations at § 412.424(d)(1)(iii)(F)(2)(i) allow an IPF to receive a temporary adjustment to its FTE cap to reflect residents added because of the closure of another IPF’s residency training program for cost reporting periods beginning on or after July 1, 2011 if—

- The IPF is training additional residents from the residency training program of an IPF that closed its program on or after July 1, 2011.
- No later than 60 days after the IPF begins to train the residents, the IPF submits to its MAC a request for a temporary adjustment to its FTE cap, documents that the IPF is eligible for this temporary adjustment by identifying the residents who have come from another IPF’s closed program and have caused the IPF to exceed its cap (or the IPF may already be in excess of its cap), specifies the length of time the adjustment is needed, and submits to its MAC a copy of the FTE cap reduction statement by the IPF closing the residency training program.

ii. IPF That Closed Its Program

The regulations at § 412.424(d)(1)(iii)(F)(2)(ii) provide that an IPF that agrees to train residents who have been displaced by the closure of another IPF’s resident teaching program may receive a temporary FTE cap adjustment only if the IPF that closed a program:

- Temporarily reduces its FTE cap based on the number of FTE residents in each program year, training in the program at the time of the program’s closure.
- No later than 60 days after the residents who were in the closed

program begin training at another IPF, submits to its MAC a statement signed and dated by its representative that specifies that it agrees to the temporary reduction in its FTE cap to allow the IPF training the displaced residents to obtain a temporary adjustment to its cap; identifies the residents who were training at the time of the program’s closure; identifies the IPFs to which the residents are transferring once the program closes; and specifies the reduction for the applicable program years.

A complete discussion on the temporary adjustment to the FTE cap to reflect residents added due to hospital closure and by residency program appears in the January 27, 2011 IPF PPS proposed rule (76 FR 5018 through 5020) and the May 6, 2011 IPF PPS final rule (76 FR 26453 through 26456).

4. Cost of Living Adjustment for IPFs Located in Alaska and Hawaii

The IPF PPS includes a payment adjustment for IPFs located in Alaska and Hawaii based upon the county in which the IPF is located. As we explained in the November 2004 IPF PPS final rule, the FY 2002 data demonstrated that IPFs in Alaska and Hawaii had per diem costs that were disproportionately higher than other IPFs. Other Medicare PPSs (for example, the IPPS and LTCH PPS) adopted a cost of living adjustment (COLA) to account for the cost differential of care furnished in Alaska and Hawaii.

We analyzed the effect of applying a COLA to payments for IPFs located in Alaska and Hawaii. The results of our analysis demonstrated that a COLA for IPFs located in Alaska and Hawaii would improve payment equity for these facilities. As a result of this analysis, we provided a COLA in the November 2004 IPF PPS final rule.

A COLA for IPFs located in Alaska and Hawaii is made by multiplying the nonlabor-related portion of the Federal per diem base rate by the applicable COLA factor based on the COLA area in which the IPF is located.

The COLA factors are published on the Office of Personnel Management

(OPM) Web site (<http://www.opm.gov/oca/cola/rates.asp>).

We note that the COLA areas for Alaska are not defined by county as are the COLA areas for Hawaii. In 5 CFR 591.207, the OPM established the following COLA areas:

- City of Anchorage, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse;
- City of Fairbanks, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse;
- City of Juneau, and 80-kilometer (50-mile) radius by road, as measured from the Federal courthouse;
- Rest of the State of Alaska.

As stated in the November 2004 IPF PPS final rule, we update the COLA factors according to updates established by the OPM. However, sections 1911 through 1919 of the Nonforeign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense Authorization Act (NDAA) for Fiscal Year 2010 (Pub. L. 111–84, October 28, 2009), transitions the Alaska and Hawaii COLAs to locality pay. Under section 1914 of Pub. L. 111–84, locality pay is being phased in over a 3-year period beginning in January 2010, with COLA rates frozen as of the date of enactment, October 28, 2009, and then proportionately reduced to reflect the phase-in of locality pay.

When we published the proposed COLA factors in the January 2011 IPF PPS proposed rule (76 FR 4998), we inadvertently selected the FY 2010 COLA rates which had been reduced to account for the phase-in of locality pay. We did not intend to propose the reduced COLA rates because that would have understated the adjustment.

Since the 2009 COLA rates did not reflect the phase-in of locality pay, we finalized the FY 2009 COLA rates for RY 2010 through RY 2014 and indicated our intent to address the COLA in FY 2015. Currently, IPFs located in Alaska and Hawaii receive the updated COLA factors based on the COLA area in which the IPF is located as shown in Table 10 below.

TABLE 10—COLA FACTORS FOR ALASKA AND HAWAII IPFS

Area	Cost of living adjustment factor
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23
Rest of Alaska	1.25
Hawaii:	

TABLE 10—COLA FACTORS FOR ALASKA AND HAWAII IPFS—Continued

Area	Cost of living adjustment factor
City and County of Honolulu	1.25
County of Hawaii	1.18
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

(The above factors are based on data obtained from the U.S. Office of Personnel Management Web site at: <http://www.opm.gov/oca/cola/rates.asp>.)

In the FY 2013 IPPS/LTCH final rule (77 FR 53700 through 53701), CMS established a methodology for FY 2014 to update the COLA factors for Alaska and Hawaii. Under that methodology, we use a comparison of the growth in the Consumer Price Indices (CPIs) in Anchorage, Alaska and Honolulu, Hawaii relative to the growth in the overall CPI as published by the Bureau of Labor Statistics (BLS) to update the COLA factors for all areas in Alaska and Hawaii, respectively. As discussed in the FY 2013 IPPS/LTCH proposed rule (77 FR 28145), because BLS publishes CPI data for only Anchorage, Alaska and Honolulu, Hawaii, our methodology for updating the COLA factors uses a comparison of the growth in the CPIs for those cities relative to the growth in the overall CPI to update the COLA factors for all areas in Alaska and Hawaii, respectively. We believe that the relative price differences between these cities and the United States (as measured by the CPIs mentioned above) are generally appropriate proxies for the relative price differences between the “other areas” of Alaska and Hawaii and the United States.

The CPIs for “All Items” that BLS publishes for Anchorage, Alaska, Honolulu, Hawaii, and for the average U.S. city are based on a different mix of

commodities and services than is reflected in the nonlabor-related share of the IPPS market basket. As such, under the methodology we established to update the COLA factors, we calculated a “reweighted CPI” using the CPI for commodities and the CPI for services for each of the geographic areas to mirror the composition of the IPPS market basket nonlabor-related share. The current composition of BLS’ CPI for “All Items” for all of the respective areas is approximately 40 percent commodities and 60 percent services. However, the nonlabor-related share of the IPPS market basket is comprised of 60 percent commodities and 40 percent services. Therefore, under the methodology established for FY 2014 in the FY 2013 IPPS/LTCH PPS final rule, we created reweighted indexes for Anchorage, Alaska, Honolulu, Hawaii, and the average U.S. city using the respective CPI commodities index and CPI services index and applying the approximate 60/40 weights from the IPPS market basket. This approach is appropriate because we continue to make a COLA for hospitals located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standardized amount by a COLA factor.

Under the COLA factor update methodology established in the FY 2014

IPPS/LTCH final rule, we adjust payments made to hospitals located in Alaska and Hawaii by incorporating a 25-percent cap on the CPI-updated COLA factors. We note that OPM’s COLA factors were calculated with a statutorily mandated cap of 25 percent, and since at least 1984, we have exercised our discretionary authority to adjust Alaska and Hawaii payments by incorporating this cap. In keeping with this historical policy, we continue to use such a cap, as our rule is based on OPM’s COLA factors. We believe this approach is appropriate because our CPI-updated COLA factors use the 2009 OPM COLA factors as a basis.

We believe it is appropriate to adopt the same methodology for the COLA factors applied under the IPPS because IPFs are hospitals with a similar mix of commodities and services. In addition, we think it is appropriate to have a consistent policy approach with that of other hospitals in Alaska and Hawaii. Therefore, we are adopting the cost of living adjustment factors shown in Table 11 below for IPFs located in Alaska and Hawaii. We are adopting the COLA rates, which were published in the FY 2014 IPPS/LTCH final rule (78 FR 50986) using the new update methodology.

TABLE 11—COST-OF-LIVING ADJUSTMENT FACTORS—ALASKA AND HAWAII HOSPITALS AREA COLA FACTOR

Area	Cost of living adjustment factor
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23
Rest of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.19
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

Final Rule Action: We did not receive any public comments on the proposed

COLA methodology and adjustment factors for IPFs in Alaska and Hawaii.

We are adopting the update

methodology and adjustment factors shown in Table 11 above.

5. Adjustment for IPFs With a Qualifying Emergency Department (ED)

The IPF PPS includes a facility-level adjustment for IPFs with qualifying EDs. We provide an adjustment to the Federal per diem base rate to account for the costs associated with maintaining a full-service ED. The adjustment is intended to account for ED costs incurred by a freestanding psychiatric hospital with a qualifying ED or a distinct part psychiatric unit of an acute care hospital or a CAH for preadmission services otherwise payable under the Medicare Outpatient Prospective Payment System (OPPS) furnished to a beneficiary on the date of the beneficiary's admission to the hospital and during the day immediately preceding the date of admission to the IPF (see § 413.40(c)(2)) and the overhead cost of maintaining the ED. This payment is a facility-level adjustment that applies to all IPF admissions (with one exception described below), regardless of whether a particular patient receives preadmission services in the hospital's ED.

The ED adjustment is incorporated into the variable per diem adjustment for the first day of each stay for IPFs with a qualifying ED. That is, IPFs with a qualifying ED receive an adjustment factor of 1.31 as the variable per diem adjustment for day 1 of each stay. If an IPF does not have a qualifying ED, it receives an adjustment factor of 1.19 as the variable per diem adjustment for day 1 of each patient stay.

The ED adjustment is made on every qualifying claim except as described below. As specified in § 412.424(d)(1)(v)(B), the ED adjustment is not made when a patient is discharged from an acute care hospital or CAH and admitted to the same hospital's or CAH's psychiatric unit. We clarified in the November 2004 IPF PPS final rule (69 FR 66960) that an ED adjustment is not made in this case because the costs associated with ED services are reflected in the DRG payment to the acute care hospital or through the reasonable cost payment made to the CAH.

Therefore, when patients are discharged from an acute care hospital or CAH and admitted to the same hospital or CAH's psychiatric unit, the IPF receives the 1.19 adjustment factor as the variable per diem adjustment for the first day of the patient's stay in the IPF.

Final Rule Action: For FY 2015, we are retaining the 1.31 adjustment factor

for IPFs with qualifying EDs. A complete discussion of the steps involved in the calculation of the ED adjustment factor appears in the November 2004 IPF PPS final rule (69 FR 66959 through 66960) and the May 2006 IPF PPS final rule (71 FR 27070 through 27072).

D. Other Payment Adjustments and Policies

1. Outlier Payments

The IPF PPS includes an outlier adjustment to promote access to IPF care for those patients who require expensive care and to limit the financial risk of IPFs treating unusually costly patients. In the November 2004 IPF PPS final rule, we implemented regulations at § 412.424(d)(3)(i) to provide a per-case payment for IPF stays that are extraordinarily costly. Providing additional payments to IPFs for extremely costly cases strongly improves the accuracy of the IPF PPS in determining resource costs at the patient and facility level. These additional payments reduce the financial losses that would otherwise be incurred in treating patients who require more costly care and, therefore, reduce the incentives for IPFs to under-serve these patients.

We make outlier payments for discharges in which an IPF's estimated total cost for a case exceeds a fixed dollar loss threshold amount (multiplied by the IPF's facility-level adjustments) plus the Federal per diem payment amount for the case.

In instances when the case qualifies for an outlier payment, we pay 80 percent of the difference between the estimated cost for the case and the adjusted threshold amount for days 1 through 9 of the stay (consistent with the median LOS for IPFs in FY 2002), and 60 percent of the difference for day 10 and thereafter. We established the 80 percent and 60 percent loss sharing ratios because we were concerned that a single ratio established at 80 percent (like other Medicare PPSs) might provide an incentive under the IPF per diem payment system to increase LOS in order to receive additional payments.

After establishing the loss sharing ratios, we determined the current fixed dollar loss threshold amount of \$10,245 through payment simulations designed to compute a dollar loss beyond which payments are estimated to meet the 2 percent outlier spending target. Each year when we update the IPF PPS, we simulate payments using the latest available data to compute the fixed dollar loss threshold so that outlier

payments represent 2 percent of total projected IPF PPS payments.

a. Update to the Outlier Fixed Dollar Loss Threshold Amount

In accordance with the update methodology described in § 412.428(d), we will update the fixed dollar loss threshold amount used under the IPF PPS outlier policy. Based on the regression analysis and payment simulations used to develop the IPF PPS, we established a 2 percent outlier policy which strikes an appropriate balance between protecting IPFs from extraordinarily costly cases while ensuring the adequacy of the Federal per diem base rate for all other cases that are not outlier cases.

Based on an analysis of the latest available data (that is, FY 2013 IPF claims) and rate increases, we believe it is necessary to update the fixed dollar loss threshold amount in order to maintain an outlier percentage that equals 2 percent of total estimated IPF PPS payments.

In the May 2006 IPF PPS final rule (71 FR 27072), we describe the process by which we calculate the outlier fixed dollar loss threshold amount. We are not changing this process for FY 2015. We begin by simulating aggregate payments with and without an outlier policy, and applying an iterative process to determine an outlier fixed dollar loss threshold amount that will result in estimated outlier payments being equal to 2 percent of total estimated payments under the simulation. Based on this process, using the FY 2013 claims data, we estimate that IPF outlier payments as a percentage of total estimated payments are approximately 1.6 percent in FY 2014. Thus, we updated the FY 2015 IPF outlier threshold amount to ensure that estimated FY 2015 outlier payments are approximately 2 percent of total estimated IPF payments. The outlier fixed dollar loss threshold amount of \$10,245 for FY 2014 changed to \$8,755 for FY 2015 to increase estimated outlier payments and thereby maintain estimated outlier payments at 2 percent of total estimated aggregate IPF payments for FY 2015.

Final Rule Action: In this final rule, we are adopting \$8,755 as the fixed dollar loss threshold amount for FY 2015.

b. Update to IPF Cost-to-Charge Ratio Ceilings

Under the IPF PPS, an outlier payment is made if an IPF's cost for a stay exceeds a fixed dollar loss threshold amount plus the IPF PPS amount. In order to establish an IPF's cost for a particular case, we multiply

the IPF's reported charges on the discharge bill by its overall cost-to-charge ratio (CCR). This approach to determining an IPF's cost is consistent with the approach used under the IPPS and other PPSs. In the June 2003 IPPS final rule (68 FR 34494), we implemented changes to the IPPS policy used to determine CCRs for acute care hospitals because we became aware that payment vulnerabilities resulted in inappropriate outlier payments. Under the IPPS, we established a statistical measure of accuracy for CCRs in order to ensure that aberrant CCR data did not result in inappropriate outlier payments.

As we indicated in the November 2004 IPF PPS final rule (69 FR 66961), because we believe that the IPF outlier policy is susceptible to the same payment vulnerabilities as the IPPS, we adopted a method to ensure the statistical accuracy of CCRs under the IPF PPS. Specifically, we adopted the following procedure in the November 2004 IPF PPS final rule: We calculated two national ceilings, one for IPFs located in rural areas and one for IPFs located in urban areas. We computed the ceilings by first calculating the national average and the standard deviation of the CCR for both urban and rural IPFs using the most recent CCRs entered in the CY 2014 Provider Specific File.

To determine the rural and urban ceilings, we multiplied each of the standard deviations by 3 and added the result to the appropriate national CCR average (either rural or urban). The upper threshold CCR for IPFs in FY 2015 is 1.8590 for rural IPFs, and 1.6582 for urban IPFs, based on CBSA-based geographic designations. If an IPF's CCR is above the applicable ceiling, the ratio is considered statistically inaccurate and we assign the appropriate national (either rural or urban) median CCR to the IPF.

We apply the national CCRs to the following situations:

- ++ New IPFs that have not yet submitted their first Medicare cost report. We continue to use these national CCRs until the facility's actual CCR can be computed using the first tentatively or final settled cost report.
- ++ IPFs whose overall CCR is in excess of 3 standard deviations above the corresponding national geometric mean (that is, above the ceiling).

- ++ Other IPFs for which the MAC obtains inaccurate or incomplete data with which to calculate a CCR.

We are not making any changes to the application of the national CCRs or to the procedures for updating the CCR ceilings in FY 2015. However, we are

updating the FY 2015 national median and ceiling CCRs for urban and rural IPFs based on the CCRs entered in the latest available IPF PPS Provider Specific File. Specifically, for FY 2015, and to be used in each of the three situations listed above, using the most recent CCRs entered in the CY 2014 Provider Specific File, we estimate the national median CCR of 0.6220 for rural IPFs and the national median CCR of 0.4710 for urban IPFs. These calculations are based on the IPF's location (either urban or rural) using the CBSA-based geographic designations.

A complete discussion regarding the national median CCRs appears in the November 2004 IPF PPS final rule (69 FR 66961 through 66964).

2. Future Refinements

For RY 2012, we identified several areas of concern for future refinement and we invited comments on these issues in our RY 2012 proposed and final rules. For further discussion of these issues and to review the public comments, we refer readers to the RY 2012 IPF PPS proposed rule (76 FR 4998) and final rule (76 FR 26432).

As we have indicated throughout this final rule, we have delayed making refinements to the IPF PPS until we have completed a thorough analysis of IPF PPS data on which to base those refinements. Specifically, we explained that we will delay updating the adjustment factors derived from the regression analysis until we have IPF PPS data that include as much information as possible regarding the patient-level characteristics of the population that each IPF serves. We have begun the necessary analysis to better understand IPF industry practices so that we may refine the IPF PPS as appropriate. Using more recent data, we plan to re-run the regression analyses and the patient- and facility-level adjustments. While we are not implementing refinements in this final rule, we expect that in the rulemaking for FY 2017 we will be ready to present the results of our analysis.

VIII. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

1. Statutory Authority

Section 1886(s)(4) of the Act, as added and amended by sections 3401(f) and 10322(a) of the Affordable Care Act, requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units. Section 1886(s)(4)(A)(i) of the Act requires that, for rate year (RY) 2014 and each subsequent rate year, the Secretary shall reduce any annual update to a

standard Federal rate for discharges occurring during the rate year by 2.0 percentage points for any inpatient psychiatric hospital or psychiatric unit that does not comply with quality data submission requirements with respect to an applicable rate year.

As noted above, section 1886(s)(4)(A)(i) of the Act uses the term "rate year." Beginning with the annual update of the inpatient psychiatric facility prospective payment system (IPF PPS) that took effect on July 1, 2011 (RY 2012), we aligned the IPF PPS update with the annual update of the ICD-9-CM codes, which are effective on October 1 of each year. The change allows for annual payment updates and the ICD-9-CM coding update to occur on the same schedule and appear in the same **Federal Register** document, thus making rule updates more administratively efficient. To reflect the change to the annual payment rate update cycle, we revised the regulations at § 412.402 to specify that, beginning October 1, 2012, the rate year update period would be the 12-month period of October 1 through September 30, which we refer to as a fiscal year (FY) (76 FR 26435). For more information regarding this terminology change, we refer readers to section III. of the RY 2012 IPF PPS final rule (76 FR 26434 through 26435).

As provided in section 1886(s)(4)(A)(ii) of the Act, the application of the reduction for failure to report under section 1886(s)(4)(A)(i) of the Act may result in an annual update of less than 0.0 percent for a fiscal year, and may result in payment rates under section 1886(s)(1) of the Act being less than the payment rates for the preceding year. In addition, section 1886(s)(4)(B) of the Act requires that the application of the reduction to a standard Federal rate update be noncumulative across fiscal years. Thus, any reduction applied under section 1886(s)(4)(A) of the Act will apply only with respect to the fiscal year rate involved and the Secretary shall not take into account the reduction in computing the payment amount under the system described in section 1886(s)(1) of the Act for subsequent years.

Section 1886(s)(4)(C) of the Act requires that, for FY 2014 (October 1, 2013, through September 30, 2014) and each subsequent year, each psychiatric hospital and psychiatric unit shall submit to the Secretary data on quality measures as specified by the Secretary. The data shall be submitted in a form and manner, and at a time, specified by the Secretary. Under section 1886(s)(4)(D)(i) of the Act, measures

selected for the quality reporting program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The National Quality Forum (NQF) currently holds this contract.

Section 1886(s)(4)(D)(ii) of the Act provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Pursuant to section 1886(s)(4)(D)(iii) of the Act, the Secretary shall publish the measures applicable to the FY 2014 IPFQR Program no later than October 1, 2012.

Section 1886(s)(4)(E) of the Act requires the Secretary to establish procedures for publishing the data submitted by inpatient psychiatric hospitals and psychiatric units under the IPFQR Program. These procedures must ensure that a facility has the opportunity to review its data prior to the data being made public. The Secretary must report quality measures that relate to services furnished by the psychiatric hospitals and units on the CMS Web site.

2. Application of the Payment Update Reduction for Failure to Report for the FY 2015 Payment Determination and Subsequent Years

Beginning in FY 2014, section 1886(s)(4)(A)(i) of the Act requires the application of a 2.0 percentage point reduction to the applicable annual update to a Federal standard rate for those psychiatric hospitals and psychiatric units that fail to comply with the quality reporting requirements implemented in accordance with section 1886(s)(4)(C) of the Act, as detailed below. The application of the reduction may result in an annual update for a fiscal year that is less than 0.0 percent and in payment rates for a fiscal year being less than the payment rates for the preceding fiscal year. Pursuant to section 1886(s)(4)(B) of the Act, any such reduction is not cumulative and will apply only to the fiscal year involved. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53678), we adopted requirements regarding the application of the payment reduction to the annual update of the standard Federal rate for failure to report data on measures selected for the FY 2014 payment determination and subsequent years, and added new

regulatory text at 42 CFR 412.424 to codify these requirements.

3. Covered Entities

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645), we established that the IPFQR Program's quality reporting requirements cover those psychiatric hospitals and psychiatric units paid under Medicare's IPF PPS (42 CFR 412.404(b)). Generally, psychiatric hospitals and psychiatric units within acute care and critical access hospitals that treat Medicare patients are paid under the IPF PPS. For more information on the application of, and exceptions to, payments under the IPF PPS, we refer readers to section IV. of the November 15, 2004 IPF PPS final rule (69 FR 66926). As we noted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645), we use the term "inpatient psychiatric facility" (IPF) to refer to both inpatient psychiatric hospitals and psychiatric units. This usage follows the terminology in our IPF PPS regulations (42 CFR 412.402).

4. Considerations in Selecting Quality Measures

In implementing the IPFQR Program, our overarching objective is to support the HHS National Quality Strategy (NQS) and CMS Quality Strategy's goal for better health care for individuals, better health for populations, and lower costs for health care services. More information on the CMS Quality Strategy can be found at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html>. Implementation of the IPFQR Program works to achieve the goals of the CMS Quality Strategy by promoting transparency around the quality of care provided at IPFs to support patient decision-making and drive quality improvement, as well as to further the alignment of quality measurement and improvement goals at IPFs with those of other health care providers.

For purposes of the IPFQR Program, section 1886(s)(4)(D)(i) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act. However, the statutory requirements under section 1886(s)(4)(D)(ii) of the Act provide an exception that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed,

provided that due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

We seek to collect data in a manner that balances the need for information related to the full spectrum of quality performance and the need to minimize the burden of data collection and reporting. We have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care provided by IPFs. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645 through 53646) for a detailed discussion of the considerations taken into account for measure development and selection.

Prior to being proposed in the proposed rule, we place our measures on a measure under consideration list, which is made public by December 1 of each year. Measures proposed for the Program were included in a publicly available document entitled "List of Measures under Consideration for December 1, 2013" in compliance with section 1890A(a)(2) of the Act. The Measure Application Partnership (MAP), a multi-stakeholder group convened by the NQF, then reviews the measures being proposed for Federal programs and provides input on those measures to the Secretary, as captured in its "MAP Pre-Rulemaking Report: 2014 Recommendations on Measures for More than 20 Federal Programs," which is available on the NQF Web site at http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx. We considered the input and recommendations provided by the MAP in selecting measures for the Program.

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5. Quality Measures

a. Quality Measures for the FY 2016 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53646 through 53652), we adopted six chart-abstracted IPF quality

measures for the FY 2014 payment determination and subsequent years.

We note that, at the time that we adopted the measures in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53258), providers were using ICD–9–CM codes. The conversion of ICD–9–CM to ICD–10–CM/PCS codes for the IPF PPS will become effective on October 1, 2015. We do not anticipate that this change will have substantive effects on any Program measures at this time. CMS will update the user manual, discussed further in section V below, to reflect any necessary measure updates. Generally, measures adopted for the IPFQR Program will remain in the Program for all subsequent years, unless and until specifically stated otherwise (for example, through removal or replacement).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50890 through 50895), we added one new chart-abstracted measure for the IPFQR Program: Alcohol Use Screening (SUB–1) (NQF #1661). We also added one new claims-based measure: Follow-Up After Hospitalization for Mental Illness (FUH) (NQF #0576). Both measures apply to the FY 2016 payment determination and subsequent years, unless and until we change them through future rulemaking.

The table below sets out the previously adopted measures.

TABLE 12—PREVIOUSLY ADOPTED QUALITY MEASURES FOR THE IPFQR PROGRAM

National quality strategy priority	NQF #	Measure ID	Measure description
Patient Safety	0640	HBIPS–2	Hours of Physical Restraint Use.*
	0641	HBIPS–3	Hours of Seclusion Use.*
Clinical Quality of Care	***0552	HBIPS–4	Patients Discharged on Multiple Antipsychotic Medications.*
	0560	HBIPS–5	Patients Discharged on Multiple Antipsychotic Medications with Appropriate Justification.*
	1661	SUB–1	Alcohol Use Screening.**
	0576	FUH	Follow-Up After Hospitalization for Mental Illness.**
Care Coordination	0557	HBIPS–6	Post-Discharge Continuing Care Plan Created.*
	0558	HBIPS–7	Post-Discharge Continuing Care Plan Transmitted to Next Level of Care Provider Upon Discharge.*

* Quality measures adopted in the FY 2013 IPPS/LTCH PPS final rule for the FY 2014 payment determination and subsequent years.

** Quality measures adopted in the FY 2014 IPPS/LTCH PPS final rule for the FY 2016 payment determination and subsequent years.

*** Measure 0552 is no longer endorsed by the NQF.

We note that in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50896 through 50897 and 50900), we also adopted for the FY 2016 payment determination and subsequent years a voluntary collection of information, IPF Assessment of Patient Experience of Care (now renamed Assessment of Patient Experience of Care), which was to be collected using a Web-Based

Measures Tool and would not affect an IPF's FY 2016 payment determination. We also noted that we intended to propose to make this a mandatory measure in future rulemaking (78 FR 50897), which we proposed in the FY 2015 IPF PPS proposed rule.

In the FY 2015 proposed rule (79 FR 26063 through 26065), we proposed two new measures to the IPFQR Program to

those already adopted for the FY 2016 payment determination and subsequent years: (1) Assessment of Patient Experience of Care; and (2) use of an Electronic Health Record. We are not removing or replacing any of the previously adopted measures from the IPFQR Program for FY 2016. These two new measures will be captured in the IPF Web-Based Measures Tool, which

can be accessed through the QualityNet home page at: <http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic/Page/QnetHomepage>. The Tool will be updated, so that when IPFs submit their data for FY 2016 (between July 1, 2015, and August 15, 2015) there will be a place to provide responses for these two structural measures.

1. Assessment of Patient Experience of Care

Improvement of experience of care for patients, families, and caregivers is one of our objectives within the CMS Quality Strategy and is not currently addressed in the IPFQR Program. Surveys of individuals about their experience in all health care settings provide important information as to whether or not high-quality, person-centered care is actually provided, and address elements of service delivery that matter most to recipients of care.

We included the measure “Inpatient Consumer Survey (ICS) Consumer Evaluation of Inpatient Behavioral Healthcare Services” (NQF #0726) in our “List of Measures under Consideration for December 1, 2012.” The measure would gather clients’ evaluation of their inpatient care based on six domains—outcome, dignity, rights, treatment, environment, and empowerment. The MAP provided input on the measure and supported its inclusion in the IPFQR Program. However, we did not propose to adopt the measure in the FY 2014 IPPS/LTCH PPS proposed rule for several reasons, including potential reporting and information collection burdens in a new program, and compatibility with the content and format of other similar CMS beneficiary surveys (78 FR 27740 and 78 FR 50896). We also recognized the challenges of measuring patient experience of care, particularly for involuntary cases and geriatric psychiatric patients suffering from dementia. In addition, we recognized that IPFs may have developed their own survey instruments, which we wanted to learn more about prior to requiring collection of a patient experience of care survey for the Program (78 FR 50897). We also indicated our intention to pursue the adoption of a standardized measure of patient experience of care for the IPFQR program in the near future for public reporting and consumer decision making purposes.

In the final rule (78 FR 50896), in an effort to proceed cautiously with the selection of an assessment instrument and collection protocol, and as an intermediate measure, we implemented a voluntary collection of information on

whether IPFs administer a detailed assessment of patient experience of care using a standardized collection protocol and a structured instrument. If the IPFs answered “Yes,” we also asked them to indicate the name of the survey that they administer. We indicated our intention to propose to change this request for voluntary information into a mandatory measure in future rulemaking. We are now requiring this request to be a structural measure for the FY 2016 payment determination.

The measure “Inpatient Psychiatric Facility Routinely Assesses Patient Experience of Care” (now, “Assessment of Patient Experience of Care”) was included on our “List of Measures under Consideration for December 1, 2013.” The measure asks IPFs whether they routinely assess patient experience of care using a standardized collection protocol and a structured instrument. The MAP supported this measure, but encouraged its eventual replacement with a robust survey of patient experience and a measure based on consumer-reported information, such as a Consumer Assessment of Healthcare Providers and Systems (CAHPS®) tool. We believe that the reporting of this measure will begin to provide information on a priority area of the HHS National Quality Strategy that is currently unaddressed in the IPFQR Program, that of patient and family engagement and experience of care. Further, the information gathered through the collection of this measure will be helpful in the development of a standardized survey of patient assessment of care that we intend to develop as a successor to this measure.

Because this is a structural measure that does not depend on systems for collecting and abstracting individual patient information, only requires simple attestation, and does not require extended time to prepare to report, we believe that it will not be burdensome to IPFs. Accordingly, we are proposing to include it as a mandatory measure for the FY 2016 payment determination, a year earlier than for other measures proposed in this rule that are dependent on these systems.

The measure is currently not NQF-endorsed. Section 1886(s)(4)(D)(ii) of the Act authorizes the Secretary to specify a measure that is not endorsed by the NQF as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topic of patient experience of care

for the IPF setting. Therefore, we believe that the Assessment of Patient Experience of Care proposed measure meets the measure selection exception requirement under section 1886(s)(4)(D)(ii) of the Act. Public comments and responses on the Patient Experience of Care Measure are summarized below.

Comment: Some commenters stated that inclusion of this structural measure was not appropriate because it was not endorsed by the NQF and not supported for use in the Program by the MAP.

Response: We believe that inclusion of this measure without NQF endorsement meets the statutory requirements under section 1886(s)(4)(D)(ii) of the Act. Under that section, the Secretary is authorized to specify a measure that is not endorsed by the NQF as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures that had been endorsed or adopted by a consensus organization, and found no other feasible and practical measures on the topic of patient experience of care for the IPF setting. In addition, this measure was proposed to collect data that will aid in the development of a future instrument that is more compatible with the content and format of other similar CMS beneficiary surveys than the Inpatient Consumer Survey (ICS) Consumer Evaluation of Inpatient Behavioral Healthcare Services.

We disagree with the commenters’ assessment that the MAP did not support inclusion of this measure. The MAP did support the measure, but encouraged its eventual replacement with a robust survey of patient experience and a measure based on consumer-reported information. As we stated in the proposed rule, we intend to develop a successor to this measure that will be specified and tested in the inpatient psychiatric setting, and that will be informed by the collection of information associated with the Assessment of Patient Experience of Care measure.

Comment: One commenter sought clarification on whether an IPF will be penalized if it does not collect patient experience of care data.

Response: An IPF will not be penalized for not collecting patient experience of care data. CMS credits IPFs for reporting this measure in the IPFQR Program applicable FY if they successfully report by the deadline whether they collect these data.

Comment: Some commenters stated that, because this measure is an

attestation measure only, it is not a quality of care measure that should be part of a requirement that affects payment and that is publicly reported. Similarly, some commenters stated that this measure would provide very limited insight to patients on the actual experience of care in IPFs.

Response: We disagree with the commenters. We believe that the potential value of a quality measure is primarily in the information that it provides, and is not necessarily limited by how it is collected or reported. CMS credits IPFs for reporting this measure in the IPFQR Program applicable FY if they successfully report by the deadline whether they collect these data. We believe that the data collected through reporting of this measure will begin to provide information on a priority area of the HHS National Quality Strategy, patient and family engagement and experience of care, which is currently unaddressed in the Program. Collection of this information will further enable the development of a successor to this measure that will provide valuable, actionable information for patients, and their families and caregivers, on the quality of care provided in IPFs.

Comment: Some commenters suggested that, instead of implementing this measure, CMS should continue its efforts to develop a standardized patient assessment survey for IPFs. In particular, some commenters suggested that CMS undertake an in-depth study of IPFs to identify not only which survey instruments are currently in use, but also the potential costs of and operational barriers to implementing such a standardized survey.

Response: We thank the commenters for their support for development of a standardized patient assessment survey for IPFs. However, we believe that implementing this Assessment of Patient Experience of Care measure at this time will significantly enhance our ability to develop such a standardized survey by providing useful information to aid in the development process. As previously stated, we are committed to developing a standardized patient assessment survey instrument for IPFs.

Comment: One commenter stated that the proposed rule does not specify what constitutes the routine assessment of patient experience of care using a standardized collection protocol and a structured instrument.

Response: By “routine assessment” we mean that administration of an experience of care instrument occurs as a regular, commonplace activity of the facility. By “standardized collection protocol” we mean that the administration of the instrument occurs

under rules or guidelines that ensure or promote comparability of individual responses. By “structured instrument” we mean that oral or written questions constituting the instrument are the same for all respondents and follow consistent rules for administration.

Comment: One commenter expressed support for this measure, but stated that IPFs should not be required to report the name of the instrument because there currently is no nationally utilized, industry standard tool. Instead, the commenter stated, it should be sufficient that an IPF demonstrate that the instrument utilized is standardized in delivery, and structured in formatting and scoring.

Response: We disagree with the commenter. We believe that reporting the name of the instrument utilized by the IPF will provide more accurate information through collecting specific survey names, as well as aiding in the process of developing a future instrument that is more compatible with the content and format of other similar CMS beneficiary surveys.

Final Rule Action: After consideration of the public comments, we are finalizing the Assessment of Patient Experience of Care measure as proposed for the FY 2016 payment determination and subsequent years.

2. Use of an Electronic Health Record

In 2009, as part of the Health Information Technology for Economic and Clinical Health (HITECH) Act, incentives were provided to encourage eligible hospitals and eligible professionals to adopt electronic health record (EHR) systems. The widespread adoption of these systems holds the potential to support multiple goals of CMS' quality strategy, including making care safer and more affordable, and promoting coordination of care. One review of over a hundred studies of the effects of EHRs showed that nearly all demonstrated positive overall results.¹ These results were most frequently demonstrated in the areas of efficiency and effectiveness of care, patient safety and satisfaction, and process of care.²

Positive results such as these depend in part on the ways in which an EHR system is used. EHRs can facilitate the use of clinical decision support tools, physician order entry systems, and health information exchange. The concept of “meaningful use” of EHRs captures the goals for which incentive

payments are made. These goals include, among others: Quality improvement, safety, and efficiency; health disparities reduction; patient and family engagement; care coordination improvement and population health; and maintenance of the privacy and security of patient health information.³

We believe that a measure of the degree of EHR implementation provides important information about an element of health care service delivery shown to be associated with the delivery of quality care. Further, we believe that it provides useful information to consumers and others in choosing among different facilities.

A key issue in EHR adoption and implementation is the use of this technology to support health information exchange. HHS has a number of initiatives designed to encourage and support the adoption of health information technology and promote nationwide health information exchange to improve health care. The Office of the National Coordinator for Health Information Technology (ONC) and CMS work to promote the adoption of health information technology. Through a number of activities, HHS is promoting the adoption of ONC-certified EHRs developed to support secure, interoperable health information exchange. While available ONC-certified EHRs are not specifically certified for IPFs and other providers who are not eligible for the Medicare and Medicaid EHR Incentive Programs, ONC has requested that the HIT Policy Committee (a Federal Advisory Committee) explore the expansion of EHR certification under the ONC HIT Certification Program, focusing on EHR certification criteria needed for long-term and post-acute care (including LTCHs), and behavioral health care providers. ONC has also proposed a Voluntary 2015 Edition EHR Certification rule (79 FR 10880) that would increase the flexibility in ONC's regulatory structure to more easily accommodate health IT certification for other types of health care settings where individual or institutional health care providers are not typically eligible to qualify for the Medicare and Medicaid EHR Incentive Programs.

While certified EHRs are not specifically certified for IPFs, we believe that many of the core functions of clinical care that are captured in EHRs are common across care settings. We believe that the use of certified EHRs by

¹ M.B. Buntin, M.F. Burke, M.C. Hoaglin, et al., “The Benefits of Health Information Technology: A Review of the Recent Literature Shows Predominantly Positive Results,” *Health Affairs*, March 2011 30(3):464–71.

² *Ibid.*

³ HealthIT.gov, “EHR Incentives & Certification: Meaningful Use Definition & Objectives.” [Internet Cited 2014 February 11]. Available from <http://www.healthit.gov/providers-professionals/meaningful-use-definition-objectives>.

IPFs (and other providers ineligible for the Medicare and Medicaid EHR Incentive Programs) can effectively and efficiently help providers improve internal care delivery practices, support the exchange of important information across care partners and during transitions of care, and could enable the reporting of electronically specified clinical quality measures (eCQMs) (as described elsewhere in this rule). More information on the proposed rule on voluntary 2015 Edition EHR Certification, identification of EHR certification criteria and development of standards applicable to IPFQRs can be found at:

- <http://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations>
- <http://www.healthit.gov/facac/facac/health-it-policy-committee/htpc-workgroups/certification-adoption>
- <http://wiki.siframework.org/LCC+LTPAC+Care+Transition+SWG>
- <http://wiki.siframework.org/Longitudinal+Coordination+of+Care>

We included the measure, “IPF Use of an Electronic Health Record Meeting Stage 1 or Stage 2 Meaningful Use Criteria” (now, “Use of an Electronic Health Record”) in the “List of Measures under Consideration for December 1, 2013.” The measure will assess the degree to which facilities employ EHR systems in their service program and use such systems to support health information exchange at times of transitions in care. It is a structural measure that only requires the facility to attest to which one of the following statements best describes the facility’s highest level typical use of an EHR system (excluding the billing system) during the reporting period, and whether this use includes the exchange of interoperable health information with a health information service provider:

- a. The facility most commonly used paper documents or other forms of information exchange (for example, email) not involving the transfer of health information using EHR technology at times of transitions in care.
 - b. The facility most commonly exchanged health information using non-certified EHR technology (that is, not certified under the ONC HIT Certification Program) at times of transitions in care.
 - c. The facility most commonly exchanged health information using certified EHR technology (certified under the ONC HIT Certification Program) at times of transitions in care.
- We will also ask IPFs to indicate whether transfers of health information

at times of transitions in care included the exchange of interoperable health information with a health information service provider (HISP).

In its 2014 report, available at <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=74634>, the MAP concluded that it does not support this measure because it does not adequately address any current needs of the Program. The MAP noted that psychiatric hospitals were excluded from the EHR Incentive Programs and imposing the measure criteria is not realistic. The MAP also expressed concerns about using quality reporting programs to collect data on systems and infrastructure, and suggested that the American Hospital Association’s survey of hospitals may be a better source for this type of data.

We disagree with the MAP’s contention that the purpose of this measure is to collect data on systems and infrastructure. The purpose of the measure is to assess the use of processes for the collection, use, and transmission of medical information that have been demonstrated to impact the quality of care, rather than to collect data on systems and infrastructure. As we have described above, many studies document the benefits of EHR use on multiple dimensions related to health care quality, and to multiple goals of CMS’ quality strategy. Additionally, this is a structural measure that does not depend on systems for collecting and abstracting individual patient information and, therefore, is not burdensome on IPFs. Accordingly, we are adopting it as a measure for FY 2016 payment determination, a year earlier than for other measures we proposed in the FY 2015 IPF PPS proposed rule.

The Use of an Electronic Health Record proposed measure is not NQF-endorsed. Section 1886(s)(4)(D)(ii) of the Act authorizes the Secretary to specify a measure that is not endorsed by the NQF as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topic of the degree to which facilities employ an EHR system in their program. Therefore, we believe that the Use of an Electronic Health Record proposed measure meets the measure selection exception requirement under section 1886(s)(4)(D)(ii) of the Act. Public comments and responses to comments on the Electronic Health Record measure are summarized below.

Comment: Some commenters stated that inclusion of this structural measure was not appropriate because it was not endorsed by the NQF and not supported for use in the Program by the MAP.

Response: As outlined in the proposed rule, we believe that inclusion of this measure without NQF-endorsement meets the statutory requirements under section 1886(s)(4)(D)(ii) of the Act. Under that section, the Secretary is authorized to specify a measure that is not endorsed by the NQF insofar as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures that had been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topic of EHR use in the IPF setting.

While the MAP did not support inclusion of this measure, we disagreed with its interpretation of the purpose of this measure. The purpose of the measure is to assess the use of processes for the collection, use, and transmission of medical information that have been demonstrated to impact the quality of care, rather than to collect data on systems and infrastructure. Many studies document the benefits of EHR use on multiple dimensions related to health care quality, and to multiple goals of CMS’ quality strategy.

Comment: Some commenters stated that IPFs are currently excluded from the Medicare EHR Incentive Program and, therefore, it is inappropriate to subject IPFs to the statutory 2.0 percentage point reduction for failure to report the measure without also permitting them to avail themselves of associated incentives. Some commenters indicated their support of this measure if CMS and the Office of the National Coordinator for Health Information Technology plan to expand the EHR Incentive Program to include IPFs.

Response: We believe that the evidence demonstrating the positive effects of EHR use on multiple aspects of medical care supports its adoption as a quality measure independent of a facility’s possible eligibility for incentives promoting such use. Further, even though current certification requirements have not explicitly considered the needs of IPFs, much of the care process in IPFs is common with that of eligible hospitals, meaning that use of existing certified EHRs can effectively and efficiently improve care.

Comment: Some commenters stated that, because this measure is an attestation only measure, it is not a quality of care measure that should be

part of a requirement that affects payment and that is publicly reported.

Response: We disagree with the commenters. CMS credits IPFs for reporting any response category indicating their current EHR use status. We believe that the potential value of a quality measure is primarily in the information that it provides, and is not necessarily limited by how it is collected or reported. Further, information collected through reporting of this measure will provide valuable information on EHR use in IPFs, which is tied to the provision of high quality care. Therefore, we believe that public reporting of this measure would provide significant insight to patients, and their families and caregivers, on the quality of care provided in IPFs.

Comment: Some commenters stated that the proposed rule does not present sufficient empirical evidence to support the conclusion that the use of currently available EHR technology platforms facilitates the delivery of a high quality of care.

Response: The use of EHRs in hospitals has proven over the years to be effective in reducing medication errors, supporting timely exchange of patient information to the next level of provider (for example, the provider who will care for the patient after discharge), and improving communication among the health care team.^{4 5} In 2008, the Substance Abuse and Mental Health Services Administration (SAMHSA) conducted a study of state mental health facilities and found that five states already have a complete EHR system in their state psychiatric hospitals and 18 states have incorporated some parts of EHRs. The study found that these systems improved the communication of information and patient safety.⁶

Final Rule Action: After consideration of the public comments, we are finalizing the Use of an Electronic Health Record measure as proposed for the FY 2016 payment determination and subsequent years.

⁴ Institute of Medicine. *Preventing Medication Errors: Quality Chasm Series*. Washington, DC: The National Academies Press, 2007.

⁵ Chaudhry B, Wang J, Wu S, Maglione M, Mojica W, Roth E, et al. *Systematic Review: Impact of Health Information Technology on Quality, Efficiency, and Costs of Medical Care*. *Ann Intern Med*. 2006;144:742–752.

⁶ Lutterman, T., Phelan, B., Berhane, A., Shaw, R., Rana, V. (2008). *Characteristics of State Mental Health Agency Data Systems*. DHHS Pub. No. (SMA) 08–4361. Rockville, MD: Center for Mental Health Services, Substance Abuse and Mental Health Services Administration. Report can be accessed at: <http://store.samhsa.gov/shin/content/SMA08-4361/SMA08-4361.pdf>.

b. Quality Measures for the FY 2017 Payment Determination and Subsequent Years

In the FY 2015 proposed rule (78 FR 26065 through 26068), we proposed four quality measures to the IPFQR Program for the FY 2017 payment determination and subsequent years: (1) Influenza Immunization (IMM–2); (2) Influenza Vaccination Coverage Among Healthcare Personnel; (3) Tobacco Use Screening (TOB–1); and (4) Tobacco Use Treatment Provided or Offered (TOB–2) and Tobacco Use Treatment (TOB–2a).

1. Influenza Immunization (IMM–2) (NQF #1659)

Increasing influenza (flu) vaccination can reduce unnecessary hospitalizations and secondary complications, particularly among high risk populations such as the elderly.⁷ Each year, approximately 226,000 people in the U.S. are hospitalized with complications from influenza, and between 3,000 and 49,000 die from the disease and its complications.⁸

Vaccination is the most effective method for preventing influenza virus infection and its potentially severe complications, and vaccination is associated with reductions in influenza among all age groups.⁹ The Advisory Committee on Immunization Practices (ACIP) recommends seasonal influenza vaccination for all persons 6 months of age and older, thereby stressing the importance of influenza prevention. Evidence from a Veteran's Affairs locked behavioral psychiatric unit with 26 patients and 40 staff during an influenza outbreak demonstrates significant room for improvement in vaccination rates among IPFs.¹⁰ In this study, 54 percent of the patients had not been vaccinated, and 36 percent of non-vaccinated patients manifested symptoms as compared with 25 percent of vaccinated patients.¹¹ We believe that the adoption of a measure that assesses

⁷ Centers for Disease Control and Prevention. "People at High Risk of Developing Flu-Related Complications." [Internet Cited 2014 February 11]. Available from http://www.cdc.gov/flu/about/disease/high_risk.htm.

⁸ Thompson WW, Shay DK, Weintraub E, Brammer L, Cox N, Anderson LJ, Fukuda. "Mortality associated with influenza and respiratory syncytial virus in the United States." *JAMA*. 2003 January 8; 289 (2): 179–186.

⁹ Centers for Disease Control and Prevention. Newsroom press release February 24, 2010. "CDC's Advisory Committee on Immunization Practices (ACIP) Recommends Universal Annual Influenza Vaccination." [Internet Cited 2010 March 3]. Available from <http://www.cdc.gov/media/pressrel/2010/r100224.htm>.

¹⁰ Risa KJ, et al. "Influenza outbreak management on a locked behavioral health unit." *Am J Infect Control* 2009;37:76–8.

¹¹ *Ibid*.

influenza immunization in the IPF setting not only works toward reducing the rate of influenza infection, but also affords consumers and others useful information in choosing among different facilities.

We included the Influenza Immunization (NQF #1659) measure in the "List of Measures under Consideration for December 1, 2013." The Influenza Immunization (IMM–2) chart-abstracted measure assesses inpatients, age 6 months and older, discharged during October, November, December, January, February, or March, who are screened for influenza vaccination status and vaccinated prior to discharge, if indicated. The numerator includes discharges that were screened for influenza vaccine status and were vaccinated prior to discharge, if indicated. The denominator includes inpatients, age 6 months and older, discharged during October, November, December, January, February, or March. The measure excludes patients who: expire prior to hospital discharge or have an organ transplant during the current hospitalization; have a length of stay greater than 120 days; are transferred or discharged to another acute care hospital; or leave Against Medical Advice (AMA). We refer readers to <https://www.qualityforum.org/QPS/1659> for further technical specifications.

The MAP gave conditional support for the measure, concluding that it is not ready for implementation because it needs more experience or testing. In its 2014 final report, the MAP recognized that influenza immunization is important for healthcare personnel and patients, but cautioned that CDC and CMS need to collaborate on adjusting specifications for reporting from psychiatric units before the measure can be included in the IPFQR Program. CMS does not agree with this recommendation. Given previous experience with the use of this measure in inpatient settings and the clarity of specifications for it, CMS does not believe that additional experience or testing is needed before implementing this measure in IPFs, or that specifications need to be further adjusted for these facilities. We also believe that comments concerning collaboration with CDC largely apply to the subsequent measure for influenza vaccination among healthcare personnel, which is explained in the discussion for that measure.

We believe that the IMM–2 measure meets the measure selection criterion under section 1886(s)(4)(D)(ii) of the Act. This section provides that, in the case of a specified area or medical topic

determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

This measure is not NQF-endorsed in the IPF setting and we could not find any other comparable measure that is specifically endorsed for the IPF setting. However, we believe that this measure is appropriate for the assessment of the quality of care furnished by IPFs for the reasons discussed above. Further, this measure has been endorsed by NQF for the "Hospital/Acute care facility" setting. Although not explicitly endorsed for use in the IPF setting, we believe that the characteristics of IPFs as distinct part units of hospitals or freestanding hospitals are similar enough to hospitals/acute care facilities that this measure may be appropriately used in such facilities. Finally, the adoption of this measure in the IPFQR Program aligns with the Hospital Inpatient Quality Reporting (HIQR) Program, which also includes this measure in its measure set. Public comments and responses to comments on the IMM-2 measure are summarized below.

Comment: Multiple commenters expressed support for inclusion of this measure. Some commenters stated that it is ready to be implemented, and that further testing or experience is not required. In addition, one commenter also stated that inclusion of this measure would further alignment with similar measures collected across multiple types of acute and post-acute care settings.

Response: We thank the commenters for their support.

Comment: Some commenters stated that this measure is not relevant to the quality of care in IPFs. In particular, some commenters stated that there is no empirically demonstrated direct, or indirect, relationship between this measure and the delivery of high quality behavioral health care in the IPF setting. Therefore, according to some commenters, this measure only provides public health value and is not an appropriate addition to the Program.

Response: We disagree with the commenters. While this measure does not speak directly to specific behavioral health care services, it provides meaningful information on the overall quality of care provided in IPFs by addressing an area directly tied to improving patient health. Accordingly,

this measure not only provides value from a public health standpoint, but speaks directly to the overall quality of care that IPFs are able to provide.

Comment: Some commenters recommended that this measure should first be pilot-tested in the IPF setting before it is proposed for adoption into the Program. The commenters stated that this measure had been adequately tested in the acute care setting, but expressed concern as to the potential for negative unintended consequences in the IPF setting without further testing.

Response: We disagree with the need to pilot test this measure in the IPF setting before adoption. We believe that the challenges associated with this measure in the acute care setting are not sufficiently distinguishable from those present in the IPF setting such that they would warrant delaying adoption at this time.

Comment: One commenter stated that adopting influenza vaccination measures for both patients and personnel may create double-reporting for facilities that have distinct inpatient units for patients and staff.

Response: We believe that simultaneous adoption of the IMM-2 and Influenza Vaccination Coverage Among HealthCare Personnel measures is appropriate because only through both can potential influenza exposure for the patient population be fully assessed. We do not perceive a potential for double-reporting in the use of the measures.

Final Rule Action: After consideration of the public comments, we are finalizing the IMM-2 measure as proposed for the FY 2017 payment determination and subsequent years.

2. Influenza Vaccination Coverage Among HealthCare Personnel (NQF #0431)

Healthcare personnel (HCP) can serve as vectors for influenza transmission because they are at risk for both acquiring influenza from patients and transmitting it to patients, and HCP often come to work when ill.¹² An early report of HCP influenza infections during the 2009 H1N1 influenza pandemic estimated that 50 percent of infected HCP had contracted the influenza virus from patients or coworkers in the health care setting.¹³

¹² Wilde JA, McMillan JA, Serwint J, et al. "Effectiveness of influenza vaccine in healthcare professionals: a randomized trial." *JAMA* 1999; 281: 908–913.

¹³ Harriman K, Rosenberg J, Robinson S, et al. "Novel influenza A (H1N1) virus infections among health-care personnel—United States, April–May 2009." *Morb Mortal Wkly Rep*. 2009; 58(23): 641–645.

Influenza virus infection is common among HCP, with evidence suggesting that nearly one-quarter of HCP were infected during influenza season, but few recalled having influenza.¹⁴ While it is difficult to precisely assess HCP influenza vaccination rates among IPFs because of varying state policies requiring hospitals to collect and report HCP vaccination coverage rates, evidence from a Veterans Affairs locked behavioral psychiatric unit with 26 patients and 40 staff during an influenza outbreak demonstrates significant room for improvement.¹⁵ In this study, only 55 percent of all staff had been vaccinated, and 22 percent of non-vaccinated staff manifested symptoms as compared with 18 percent of vaccinated staff.¹⁶ We believe that the adoption of a measure that assesses influenza vaccination among HCP in the IPF setting not only works toward improving the rate at which non-vaccinated HCP manifest symptoms as compared with vaccinated HCP, but also affords consumers and others useful information in choosing among different facilities.

We included the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) measure in the "List of Measures under Consideration for December 1, 2013." The measure assesses the percentage of HCP who receive the influenza vaccination. The measure is designed to ensure that reported HCP influenza vaccination percentages are consistent over time within a single healthcare facility, as well as comparable across facilities. The numerator includes HCP in the denominator population who, during the time from October 1 (or when the vaccine became available) through March 31 of the following year:

a. Received an influenza vaccination administered at the healthcare facility, or reported in writing (paper or electronic) or provided documentation that influenza vaccination was received elsewhere;

b. Were determined to have a medical contraindication/condition of severe allergic reaction to eggs or to other component(s) of the vaccine, or history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination;

c. Declined influenza vaccination; or

¹⁴ Elder AG, O'Donnell B, McCruden EA, et al. "Incidence and recall of influenza in a cohort of Glasgow health-care workers during the 1993–4 epidemic: results of serum testing and questionnaire." *BMJ*. 1996; 313:1241–1242.

¹⁵ Risa KJ, et al. "Influenza outbreak management on a locked behavioral health unit." *Am J Infect Control* 2009;37:76–8.

¹⁶ *Ibid*.

d. Had an unknown vaccination status or did not otherwise fall under any of the abovementioned numerator categories.

The denominator includes the number of HCP working in the healthcare facility for at least one working day between October 1 and March 31 of the following year, regardless of clinical responsibility or patient contact, and is calculated separately for employees, licensed independent practitioners, and adult students/trainees and volunteers. The measure has no exclusions. We refer readers to <https://www.qualityforum.org/QPS/0431> and the CDC Web site (<http://www.cdc.gov/nhsn/PDFs/HPS-manual/vaccination/HPS-flu-vaccine-protocol.pdf>) for further technical specifications.

The MAP gave conditional support for the measure, concluding that it is not ready for implementation because it needs more experience or testing. In its 2014 report, the MAP recognized that influenza immunization is important for healthcare personnel and patients, but cautioned that CDC and CMS need to collaborate on adjusting specifications for reporting from psychiatric units before the measure can be included in the IPFQR Program. CMS does not agree with this recommendation. As explained for the IMM-2 measure, given previous experience with the use of this measure and the clarity of its specifications, CMS does not believe that additional experience or testing is needed before implementing this measure in IPFs, or that specifications need to be further adjusted for these facilities. In response to comments concerning collaboration with CDC, CDC and CMS have conferred on this issue and language has been added to the description of this measure below that clarifies that IPFs will use the CDC National Healthcare Safety Network (NHSN) infrastructure and protocol to report the measure for IPFQR Program purposes. Neither CMS nor CDC believes that there are any coordination issues remaining for the implementation of this measure.

We believe that the Influenza Vaccination Coverage Among Health Care Personnel proposed measure meets the measure selection criterion under section 1886(s)(4)(D)(ii) of the Act. This section provides that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so

endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

This measure is not NQF-endorsed in the IPF setting and we could not find any other comparable measure that is specifically endorsed for the IPF setting. However, we believe that this measure is appropriate for the assessment of the quality of care furnished by IPFs for the reasons discussed above. Further, this measure has been endorsed by NQF for the "Hospital/Acute care facility" setting. Although not explicitly endorsed for use in IPF settings, we believe that the characteristics of IPFs as distinct part units of hospitals or freestanding hospitals mean that this measure may be appropriately used in such facilities.

IPFs will use the CDC National Healthcare Safety Network (NHSN) infrastructure and protocol to report the measure for IPFQR Program purposes. The IPF reporting of HCP influenza vaccination summary data to NHSN will begin for the 2015–2016 influenza season, from October 1, 2015, to March 31, 2016, with a reporting deadline of May 15, 2016. Although the collection period for this measure extends into the first quarter of the following calendar year, this measure data will be included with other measures that will be required for FY 2017 payment determination. Similarly, reporting for subsequent years will include results for the influenza season that begins in the last quarter of the applicable calendar year's reporting.

The adoption of this measure in the IPFQR Program will align with the HIQR, the Hospital Outpatient Quality Reporting (HOQR), and the Ambulatory Surgical Center Quality Reporting (ASCQR) Programs. The Influenza Vaccination Coverage Among Healthcare Personnel (HCP) (NQF #0431) measure was finalized for the HIQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51636), and the HOQR Program in the CY 2014 OPPI/ASC final rule (78 FR 75099), and the ASCQR Program in the CY 2013 Hospital Outpatient Prospective Payment final rule (77 FR 68495).

We are aware of public concerns about the burden of separately collecting healthcare personnel (HCP) influenza vaccination status across inpatient and outpatient settings, in particular, distinguishing between the inpatient and outpatient setting personnel for reporting purposes. We also understand that some are unclear about how the measure will be reported to CDC's NHSN.

We believe reporting a single vaccination count for each healthcare facility by each individual facility's CMS Certification Number (CCN) will be less burdensome to IPFs than requiring them to distinguish between their inpatient and outpatient personnel. Therefore, beginning with the 2015–2016 influenza season, IPFs will collect and report all HCP under each individual IPF's CCN and submit this single number to CDC's NHSN. For each CMS CCN, a percentage of the HCP who received an influenza vaccination will be calculated and publically reported, so that the public will know what percentage of the HCP have been vaccinated in each IPF. We believe this will provide meaningful data that would help inform the public and healthcare facilities, while improving the quality of care. Specific details on data submission for this measure can be found in an Operational Guidance available at: <http://www.cdc.gov/nhsn/acute-care-hospital/hcp-vaccination/> and at <http://www.cdc.gov/nhsn/acute-care-hospital/index.html>.

Public comments and responses to comments on the Influenza Vaccination Coverage Among Healthcare Personnel measure are summarized below.

Comment: Multiple commenters supported the adoption of this measure. Some commenters stated that its proposed timeline promotes alignment across quality reporting programs and that the public reporting of an overall vaccination rate for a facility will provide meaningful data to inform the public on the quality of care provided by the IPF. Some commenters also expressed support for CMS' intention to allow reporting as a single vaccination count for each healthcare facility by each individual facility CCN because it will simplify data collection for facilities with multiple care settings. In addition, some commenters stressed that inclusion of this measure would further alignment with similar measures collected across multiple types of acute and post-acute care settings.

Response: We thank the commenters for their support.

Comment: Some commenters expressed concern over the burden on facilities to require documentation of vaccination status for volunteers at their facilities. One commenter stated that the measure should either exclude volunteers from its requirements or be limited only to volunteers who spend a substantial portion of time at a facility over the course of a year.

Response: We understand the commenters' concern and are cognizant of the burden associated with reporting on this measure. However, because of

the known benefits of vaccination and the fact that adoption of this measure furthers alignment across quality reporting programs, we believe that its inclusion in the Program is appropriate. Furthermore, we believe that limiting the scope of this measure with regard to volunteers would undercut the purpose of the measure. By being present in facilities, and interacting with patients and other personnel, the vaccination status of volunteers is effectively as important as that of other healthcare personnel, regardless of the amount of time spent in the facility.

Comment: Some commenters stated that this measure is not pertinent to the quality of care in IPFs. In particular, some commenters stated that there is no empirically demonstrated direct, or indirect, relationship between this measure and the delivery of high quality behavioral health care in the IPF setting. Therefore, according to some commenters, this measure only provides public health value and is not an appropriate addition to the Program.

Response: We disagree with the commenters. While this measure does not speak directly to specific behavioral health care services, it provides meaningful information on the overall quality of care provided at IPFs by addressing an area tied directly to improving patient health. Accordingly, this measure not only provides value from a public health standpoint, but speaks directly to the overall quality of care that any given IPF is able to provide.

Comment: Some commenters sought clarification on which individuals were considered 'healthcare personnel' for purposes of reporting on this measure.

Response: Clarification as to which individuals are considered healthcare personnel for purposes of this measure can be found at: <http://www.cdc.gov/nhsn/PDFs/HPS-manual/vaccination/HPS-flu-vaccine-protocol.pdf>.

Comment: Some commenters recommended that this measure should first be pilot-tested in the IPF setting before adoption into the Program.

Response: We disagree with the need to first pilot-test this measure in the IPF setting before adoption. We believe that the challenges associated with this measure in the acute care setting are not sufficiently distinguishable from those present in the IPF setting such that they would warrant delaying adoption at this time.

Comment: Some commenters stated that, while reporting this measure under IPFs' CCN to the CDC's NHSN may simplify reporting, reporting will depend on how the facility chooses to bill for the services. For instance, an

acute care hospital with an IPF unit may choose to bill under one CCN, or have one CCN for the acute care hospital and another CCN for the IPF. Therefore, commenters suggested, CMS should make both values available through QualityNet prior to public reporting, so that facilities can reconcile any differences.

Response: We understand the commenters' concerns. However, we believe that reporting this measure under IPFs' CCN to the CDC's NHSN best promotes efficiency and accuracy of data collection.

Final Rule Action: After consideration of the public comments, we are finalizing the Influenza Vaccination Coverage Among HealthCare Personnel measure as proposed for the FY 2017 payment determination and subsequent years.

3. Tobacco Use Screening (TOB-1) (NQF #1651)

Tobacco use is currently the single greatest cause of disease in the U.S., accounting for more than 435,000 deaths annually.¹⁷ Smoking is a known cause of multiple cancers, heart disease, stroke, complications of pregnancy, chronic obstructive pulmonary disease, other respiratory problems, poorer wound healing, and many other diseases.¹⁸ This health issue is especially important for persons with mental illness and substance use disorders. One study has estimated that these individuals are twice as likely to smoke as the rest of the population.¹⁹ Tobacco use also creates a heavy cost to both individuals and society. Smoking-attributable health care expenditures are estimated at \$96 billion per year in direct medical expenses and \$97 billion in lost productivity.²⁰

Strong and consistent evidence demonstrates that timely tobacco

dependence interventions for patients using tobacco can significantly reduce the risk of suffering from tobacco-related disease, as well as provide improved health outcomes for those already suffering from a tobacco-related disease.²¹ Research demonstrates that tobacco users hospitalized with psychiatric illnesses who enter into treatment can successfully overcome their tobacco dependence.²² Evidence also suggests that tobacco cessation treatment does not increase, and may even decrease, the risk of rehospitalization for tobacco users hospitalized with psychiatric illnesses.²³ Research further demonstrates that effective tobacco cessation support across the care continuum can be provided with only a minimal additional effort and without harm to the mental health recovery process.²⁴ We believe that the adoption of a measure that assesses tobacco use screening among patients of IPFs encourages the uptake of tobacco cessation treatment and its attendant benefits. We further believe that the reporting of this measure will afford consumers and others useful information in choosing among different facilities.

The Tobacco Use Screening (TOB-1) chart-abstracted measure assesses hospitalized patients who are screened within the first three days of admission for tobacco use (cigarettes, smokeless tobacco, pipe, and cigar) within the previous 30 days. The numerator includes the number of patients who were screened for tobacco use status within the first 3 days of admission. The denominator includes the number of hospitalized inpatients 18 years of age and older. The measure excludes patients who: Are less than 18 years of age; are cognitively impaired; have a duration of stay less than or equal to 3 days, or greater than 120 days; or have Comfort Measures Only documented.

We refer readers to http://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures.aspx for further details on measure specifications.

²¹ U.S. Department of Health and Human Services. "The health consequences of smoking: a report of the Surgeon General." Atlanta, GA, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2004.

²² Prochaska, JJ, et al. "Efficacy of Initiating Tobacco Dependence Treatment in Inpatient Psychiatry: A Randomized Controlled Trial." Am. J. Pub. Health. 2013 August 15; e1-e9.

²³ *Ibid.*

²⁴ *Ibid.*

¹⁷ Centers for Disease Control and Prevention. "Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 2000–2004." Morb Mortal Wkly Rep. 2008. 57(45): 1226–1228. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm>.

¹⁸ U.S. Department of Health and Human Services. "The health consequences of smoking: a report of the Surgeon General." Atlanta, GA, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2004.

¹⁹ Lasser K, Boyd JW, Woolhandler S, Himmelstein, DU, McCormick D, Bor DH. Smoking and mental illness: A population-based prevalence study. JAMA. 2000;284(20):2606–2610.

²⁰ Centers for Disease Control and Prevention. "Best Practices for Comprehensive Tobacco Control Programs—2007." Atlanta, GA, Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2007.

In the “List of Measure under Consideration for December 1, 2013,” we originally proposed a similar measure to that finalized here, which was “Preventive Care & Screening: Tobacco Use: Screening & Cessation Intervention (NQF 0028).” However, the MAP determined that this measure did not meet the needs of the program and instead recommended that we adopt an alternate measure from the Joint Commission’s suite of measures for inpatient settings, which we are now finalizing. This measure, and the following one (TOB–2 and 2a), best reflect the activities encompassed by the original NQF 0028 measure.

The measure was NQF-endorsed on March 7, 2014, and meets the measure selection criterion under section 1886(s)(4)(D)(i) of the Act. Public comments and responses to comments on the TOB–1 measure are summarized below.

Comment: One commenter stated that this measure requires labor-intensive manual chart abstraction, does not permit sampling, and does not benefit from data validation of aggregately submitted data. Without sampling, the commenter further stated that facilities will have to invest valuable resources abstracting data that has not been validated for accuracy for public reporting and possible future payment penalty.

Response: We understand the commenter’s concern with regard to the burden associated with reporting on this measure. We believe, however, that this measure strikes an appropriate balance between encouraging the uptake of tobacco cessation treatment and its documented benefits without unnecessarily burdening facilities. We also understand the commenter’s concern with regard to the unavailability of validation. We are aware of this issue and currently are working toward developing a validation methodology for future use in the Program.

Comment: Some commenters stated that this measure does not provide meaningful information on the quality of care provided in IPFs. Similarly, some commenters stated that screening for tobacco use is important for the IPF patient population, but asserted that this should be an individualized part of a patient’s care. One commenter also stated that this measure has limitations, such as not being developed and tested in the IPF setting and only applying to patients 18 years old and older, that affect its utility.

Response: We disagree with the commenters. We believe that reporting of this measure will yield information

that provides meaningful distinctions in the quality of care provided across IPFs and address an important health behavior for persons with mental illness. Precisely because tobacco use screening is considered an essential step in the care process for IPF patients, we believe that it is critical for patients, and their families and caregivers, to have accurate available information on whether IPFs integrate this into their care processes. Moreover, we do not believe that the limitations that the commenter noted substantially discount the value of this measure for the Program.

Comment: Some commenters stated that, while screening for tobacco use in the IPF setting is important, the HBIPS–1 measure is a better alternative because it is already collected by most IPFs, captures much of the information on tobacco use that CMS seeks to collect, and facilitates a more holistic approach to addressing tobacco use.

Response: We disagree with the commenters. The HBIPS–1 measure does not explicitly provide for tobacco screening and intervention. Please refer to the following link http://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures.aspx for further details on HBIPS–1 measure specifications.

Comment: One commenter stated that the burden for reporting this measure is too great because documenting a generic assessment of whether a patient uses smokeless tobacco or cigarettes should be enough of an assessment to determine if counseling or treatment for cessation should be provided.

Response: We disagree with the commenter. We believe that the requirements associated with reporting on this measure strike a reasonable balance between provider burden and providing useful information to the public on the quality of care provided in IPFs.

Final Rule Action: After consideration of the public comments, we are finalizing the TOB–1 measure as proposed for the FY 2017 payment determination and subsequent years.

4. Tobacco Use Treatment Provided or Offered (TOB–2) and Tobacco Use Treatment (TOB–2a) (NQF #1654)

As stated in our discussion of the proposed TOB–1 measure, tobacco use is currently the single greatest cause of disease in the U.S. We also indicated that research demonstrates that timely tobacco cessation treatment for hospitalized tobacco users with psychiatric illnesses may decrease the risk of rehospitalization, have only a

minimal additional effort, and not harm the mental health recovery process. We believe that the adoption of a measure that assesses tobacco use screening treatment among IPFs encourages the uptake of tobacco cessation treatment and its attendant benefits. We further believe that the reporting of this measure will afford consumers and others useful information in choosing among different facilities.

The Tobacco Use Treatment Provided or Offered (TOB–2) and Tobacco Use Treatment (TOB–2a) chart-abstracted measure is reported as an overall rate that includes all patients to whom tobacco use treatment was provided, or offered and refused, and a second rate, a subset of the first, which includes only those patients who received tobacco use treatment. The overall rate, TOB–2, assesses patients identified as tobacco product users within the past 30 days who receive or refuse practical counseling to quit, and receive or refuse Food and Drug Administration (FDA)-approved cessation medications during the first 3 days following admission. The numerator includes the number of patients who received or refused practical counseling to quit, and received or refused FDA-approved cessation medications during the first 3 days after admission.

The second rate, TOB–2a, assesses patients who received counseling and medication, as well as those who received counseling and had reason for not receiving the medication during the first 3 days following admission. The numerator includes the number of patients who received practical counseling to quit and received FDA-approved cessation medications during the first 3 days after admission.

The denominator for both TOB–2 and TOB–2a includes the number of hospitalized inpatients 18 years of age and older identified as current tobacco users. The measure excludes patients who: Are less than 18 years of age; are cognitively impaired; are not current tobacco users; refused or were not screened for tobacco use during the hospital stay; have a duration of stay less than or equal to 3 days, or greater than 120 days; or have Comfort Measures Only documented.

We refer readers to http://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures.aspx for further details on measure specifications.

The measure was NQF-endorsed on March 7, 2014, and meets the measure selection criteria under section 1886(s)(4)(D)(i) of the Act. We also note that at this time we are not adopting two

other tobacco treatment measures that are part of the set from which TOB–1, TOB–2 and TOB2a are taken. We believe that the two measures we are finalizing best encompass the activities that we originally proposed to measure through the use of the NQF 0028 measure, and best assess activities demonstrated to produce positive results in tobacco use reduction. Additionally, we believe that the other measure represents a significantly greater collection and reporting burden. Public comments and responses to comments on the TOB–2 and TOB–2a measures are summarized below.

Comment: One commenter stated that this measure requires labor-intensive manual chart abstraction, does not permit sampling, and does not benefit from data validation of aggregately submitted data. Without sampling, the commenter further argued, facilities will have to invest valuable resources abstracting data that has not been validated for accuracy for public reporting and possible future payment penalty.

Response: We understand the commenter's concern with regard to the burden associated with reporting on this measure. However, we believe that this measure strikes an appropriate balance between encouraging the uptake of tobacco cessation treatment, providing consumers with relevant and actionable information about this aspect of quality, and its documented benefits without unnecessarily burdening facilities.

Comment: Some commenters stated that this measure does not provide meaningful information on the quality of care provided in IPFs. Similarly, some commenters stated that tobacco

use treatment is important for the IPF patient population, but asserted that this should be an individualized part of a patient's care. One commenter also stated that this measure has limitations, such as not being developed and tested in the IPF setting and applying only to patients 18 years old and older, that affect its utility.

Response: We disagree with the commenters. We believe that reporting of this measure will yield information that provides meaningful distinctions in the quality of care provided across IPFs and does not conflict with the inclusion of cessation treatment within an individualized plan of care. Precisely because tobacco use cessation treatment is considered an essential step in the care process for IPF patients, we believe that it is critical for patients, and their families and caregivers, to have accurate available information on whether IPFs integrate this into their care processes. Moreover, we do not believe that the limitations that the commenter noted substantially discount the value of this measure for the Program.

Comment: Some commenters stated that, while tobacco use treatment in the IPF setting is important, the HBIPS–1 measure is a better alternative because it is already collected by most IPFs, captures much of the information on tobacco use that CMS seeks to collect, and facilitates a more holistic approach to addressing tobacco use.

Response: We disagree with the commenters. Importantly, the HBIPS–1 measure does not explicitly provide for tobacco screening and intervention. Therefore, we believe that the TOB–2 and TOB–2a measures more adequately align with the Program's reporting goals.

Please refer to the following link: http://www.jointcommission.org/specifications_manual_for_national_hospital_inpatient_quality_measures.aspx for further details on HBIPS–1 measure specifications.

Comment: One commenter stated that the abstraction burden for reporting this measure is too great because documenting a generic assessment of whether a patient uses smokeless tobacco or cigarettes should be enough of an assessment to determine if counseling or treatment for cessation should be provided.

Response: We disagree with the commenter. We believe that the requirements associated with reporting on this measure strike a reasonable balance between provider burden and providing useful information to the public on the quality of care provided in IPFs.

Final Rule Action: After consideration of the public comments, we are finalizing the TOB–2 and TOB–2a measure as proposed for the FY 2017 payment determination and subsequent years.

c. Summary of Measures

In addition to the eight measures that we previously finalized for the IPFQR Program, we are adding two new measures for reporting for the FY 2016 payment determination and subsequent years. We are also adding four new measures for the FY 2017 payment determination and subsequent years. The tables below list the new measures for the FY 2016 and FY 2017 payment determinations and subsequent years.

TABLE 13—NEW QUALITY MEASURES FOR THE IPFQR PROGRAM FOR FY 2016 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

National quality strategy priority	NQF #	Measure ID	Measure description
Patient- and Caregiver-Centered Experience of Care	N/A	N/A	Assessment of Patient Experience of Care.
Effective Communication and Coordination of Care	N/A	N/A	Use of an Electronic Health Record.

TABLE 14—NEW QUALITY MEASURES FOR THE IPFQR PROGRAM FOR FY 2017 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

National quality strategy priority	NQF #	Measure ID	Measure description
Population/Community Health	1659	IMM–2	Influenza Immunization.
Population/Community Health	0431	N/A	Influenza Vaccination Coverage Among Healthcare Personnel.
Clinical Quality of Care	1651	TOB–1	Tobacco Use Screening.
Clinical Quality of Care	1654	TOB–2	Tobacco Use Treatment Provided or Offered
		TOB–2a	and Tobacco Use Treatment.

Public comments and responses to comments on the new measures for FY 2016 and FY 2017 payment

determinations and subsequent years are summarized below.

Comment: Some commenters expressed concern that CMS has proposed too many process measures at

the expense of outcome measures. One commenter recommended that CMS should evaluate critically the extent to which potential measures will contribute to meaningful differences in the health outcomes achieved by IPF patients. This commenter further noted that CMS should be mindful of the burden associated with proposing new measures for the Program.

Response: We agree with the commenter that concern for measuring health outcomes should play an important role in measure development. To this end, as we stated in the proposed rule, we intend to propose the addition of a readmissions measure to the Program through future rulemaking. Further, we continue to welcome recommendations for the adoption of other outcome measures for inpatient psychiatric care.

We also understand the commenter's concern regarding the reporting burden associated with complying with the Program's requirements. We are mindful that the reporting burden can be particularly acute for the many small IPFs that participate in the Program. Accordingly, we have endeavored to keep the number of measures in the Program at a manageable number that is far fewer than is required for many other quality reporting programs. In considering how to expand the Program's measure set in future years, we intend to strike a balance between developing a measure set that adequately assesses the quality of care provided in IPFs, while not requiring IPFs to report on unnecessary or duplicative measures.

Comment: Some commenters requested that more time be afforded to IPFs before data collection on new measures is required.

Response: The Program's data collection requirements for new measures are consistent with policies adopted in other quality reporting programs. The period from the adoption of final measures to the beginning of the applicable reporting period typically exceeds four months. Depending on the individual facility's practices, actual data collection may take place significantly after this period.

d. Additional Procedural Requirements for the FY 2017 Payment Determination and Subsequent Years

In addition to the quality measures that we have described above, IPFs must, when they begin reporting for the FY 2017 payment determination, submit to CMS aggregate population counts for Medicare and non-Medicare discharges by age group, diagnostic group, and quarter, and sample size counts for

measures, for which sampling is performed (as is allowed for in HBIPS–4–7, and SUB–1). These requirements are separate from those described under subsection (c) of the section entitled “Form, Manner, and Timing of Quality Data Submission.” That subsection describes the population, sample size, and minimum reporting case threshold requirements for individual measures, while this section describes the collection of general population and sampling data that will assist in determining compliance with those requirements. We believe that it is vital for IPFs to accurately determine and submit to CMS their population and sampling size data in order for CMS to assess IPFs' data reporting completeness for their total population, both Medicare and non-Medicare. In addition to helping to better assess the quality and completeness of measure data, we expect that this information will improve our ability to assess the relevance and impact of potential future measures. For example, understanding that the size of subgroups of patients addressed by a particular measure varies greatly over time could be helpful in assessing the stability of reported measure values, and subsequent decisions concerning measure retention. Similarly, better understanding of the size of particular subgroups in the overall population will assist us in making choices among potential future measures specific to a particular subgroup (e.g., those with depression).

Furthermore, the form, manner, and timing of this submission will follow the policies discussed at section VIII of this preamble, and that failure to provide this information will be subject to the 2.0 percentage point reduction in the annual update for any IPF that does not comply with quality data submission requirements, pursuant to section 1886(s)(4)(A)(i) of the Act. Public comments and responses to comments on the additional procedural requirements for the FY 2017 payment determination and subsequent years are summarized below.

Comment: Some commenters expressed support for the adoption of the requirement that IPFs must submit to CMS aggregate population counts for Medicare and non-Medicare discharges by age group, diagnostic group, and quarter, and sample size counts for measures for which sampling is performed.

Response: We thank the commenters for their support.

Comment: Some commenters stated that the requirement for IPFs to submit to CMS aggregate population counts for Medicare and non-Medicare discharges

by age group, diagnostic group, and quarter, and sample size counts for measures for which sampling is performed is an inefficient use of a quality reporting program and, instead, this information would be more properly gathered through other means not tied to public reporting and under the Program's statutory penalty for failure to report IPFQR quality measure data and meet other program requirements. Similarly, some commenters further stated that this requirement would be unique among quality reporting programs.

Response: We disagree with the commenters. We believe that collection of this information will not only work to better assess the quality and completeness of measure data, but also improve our ability to assess the relevance and impact of potential future measures. Moreover, collection of this type of information is not unprecedented among quality reporting programs. For instance, the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) made a similar proposal in the FY 2015 IPPS proposed rule (79 FR 28259).

Comment: Some commenters recommended that the specifications for this data submission should mirror the same elements collected by The Joint Commission (TJC).

Response: We do not have plans at this time to align our data submission with that of TJC, but will consider their requirements in providing direction concerning these submissions.

Comment: Due to the Program's statutory penalty for failure to report IPFQR quality measure data and meet other program requirements, some commenters stated that CMS should specify its data validation approach before requiring submission of this information. The commenters further stated that the results of a validation methodology should be a factor in determining whether a statutory penalty should be assessed.

Response: We disagree with the commenters. While we are working toward developing a validation methodology for use in future Program years, we do not believe that submission of these data warrants being delayed until implementation of such a methodology.

Final Rule Action: After consideration of the public comments, we are finalizing the requirement for IPFs to submit to CMS aggregate population counts for Medicare and non-Medicare discharges by age group, diagnostic group, and quarter, and sample size counts for measures for which sampling is performed as proposed for the FY

2017 payment determination and subsequent years.

e. Maintenance of Technical Specifications for Quality Measures

We will provide a user manual that will contain links to measure specifications, data abstraction information, data submission information, a data submission mechanism known as the Web-based Measures Tool, and other information necessary for IPFs to participate in the IPFQR Program. This manual will be posted on the QualityNet Web site at: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772250192>. We will maintain the technical specifications for the quality measures by updating this manual periodically and including detailed instructions for IPFs to use when collecting and submitting data on the required measures. These updates will be accompanied by notifications to IPFQR Program participants, providing sufficient time between the change and effective dates in order to allow users to incorporate changes and updates to the measure specifications into data collection systems.

Many of the quality measures used in different Medicare and Medicaid reporting programs are endorsed by the National Quality Forum (NQF). As part of its regular maintenance process for endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and will confirm existing or minor specification changes with NQF on an annual basis. NQF solicits information from measure stewards for annual reviews, and it reviews measures for continued endorsement in a specific 3-year cycle.

We note that NQF's annual or triennial maintenance processes for endorsed measures may result in the NQF requiring updates to the measures in order to maintain endorsement status. We believe that it is important to have in place a subregulatory process to incorporate non-substantive updates required by the NQF into the measure specifications we have adopted for the IPFQR Program, so that these measures remain up-to-date.

We also recognize that some changes the NQF might require to its endorsed measures are substantive in nature and might not be appropriate for adoption

using a subregulatory process. Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53503 through 53505), we finalized a policy under which we will use a subregulatory process to make only non-substantive updates to measures used for the IPFQR Program (77 FR 53653). With respect to what constitutes substantive versus non-substantive changes, we expect to make this determination on a case-by-case basis. Examples of non-substantive changes to measures might include updates to diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure. We believe that non-substantive changes may include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based. As stated in the FY 2013 IPPS/LTCH PPS final rule, we will revise the manual, so that it clearly identifies the updates and provides links to where additional information on the updates can be found. We will also post the updates on the QualityNet Web site at <https://www.QualityNet.org>. We will provide 6 months for facilities to implement changes where changes to the data collection systems are necessary.

We will continue to use rulemaking to adopt substantive updates required by the NQF to the endorsed measures that we have adopted for the IPFQR Program. Examples of changes that we might consider to be substantive are those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent (for example, changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change would be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice. These policies regarding what is considered substantive versus non-substantive would apply to all measures in the IPFQR Program. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process.

We believe that this policy adequately balances our need to incorporate technical updates to all Program measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally

adopted. Public comments and our responses are summarized below.

Comment: One commenter expressed support for use of the Specifications Manual in the Program.

Response: We thank the commenter for its support.

Comment: One commenter recommended that CMS provide a more detailed Specifications Manual that would, for instance, include more robust definitions, and explanations of measures and data requirements.

Response: We thank the commenter for its recommendation. Once finalized, CMS will review the Specifications Manual on a regular basis and make updates as necessary.

6. New Quality Measures for Future Years

As we have previously indicated, we seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the IPF setting. Therefore, through future rulemaking, we intend to propose new measures that will help further our goal of achieving better health care and improved health for Medicare beneficiaries who obtain inpatient psychiatric services through the widespread dissemination and use of quality information.

As part of the 2013 Measures under Consideration (http://www.qualityforum.org/Setting_Priorities/Partnership/Measures_Under_Consideration_List.aspx), we identified 10 possible measures for the IPFQR Program. We are finalizing four of these measures for adoption in this final rule. Five of the measures are currently undergoing testing, and we anticipate that one or more would be adopted in the near future. These measures are:

- Suicide Risk Screening completed within one day of admission
- Violence Risk Screening completed within one day of admission
- Drug Use Screening completed within one day of admission
- Alcohol Use Screening completed within one day of admission
- Metabolic Screening

We also are currently planning to develop a 30-day psychiatric readmission measure. Similar to readmission measures currently in use for other CMS quality reporting programs, such as the HIQR Program, we envision that this measure will encompass all 30-day readmissions for discharges from IPFs, including readmissions for non-psychiatric diagnoses. Additionally, we intend to develop a standardized survey of patient

experience of care tailored for use in inpatient psychiatric settings, but also sharing elements with similar surveys in use in other CMS reporting programs.

We further anticipate that we will recommend additional measures for development or adoption in the future. We intend to develop a measure set that effectively assesses IPF quality across the range of services and diagnoses, encompasses all of the goals of the CMS quality strategy, addresses measure gaps identified by the MAP and others, and minimizes collection and reporting burden. Finally, we may propose the removal of some measures in the future, should one or more no longer reflect significant variation in quality among IPFs, or prove to be less effective than alternative measures in measuring the intended focus area. Public comments and responses to comments on new quality measures for future years are summarized below.

Comment: CMS received several comments in response to our proposal for new quality measures for future years. Some commenters stated that a number of the measures noted as currently undergoing testing address areas included in the HBIPS–1 measure and; therefore, would be unnecessarily duplicative. One commenter asserted that HBIPS–1 also contains additional areas of screening that are important for all patients and, as an integrated, comprehensive set of screens, would provide a clinical picture of the patient that any individual screen by itself could not provide. Disaggregating this measure into separate measures, according to the commenter, would introduce the potential for weakening the screening process. In addition, the commenter noted that HBIPS–1 provides very similar screenings to the measures currently undergoing testing, but within 3 days of admission, which is more appropriate for the IPF setting. In addition, the commenter stated that the metabolic screening measure that is currently undergoing testing should be limited to anthropomorphic screening.

Some commenters recommended that CMS should not include the five measures currently undergoing testing in the Program until they have been approved by the MAP and endorsed by the NQF. Another commenter stated that adopting the measures that are currently undergoing testing may result in unnecessary laboratory work for IPFs and; therefore, would increase the cost of health care services. One commenter recommended that, with regard to the measures that are currently undergoing testing, CMS consider a three-day timeframe for assessment, as opposed to

a one-day timeframe, as part of the measure specifications.

We also received a comment supporting the inclusion of a readmissions measure that focuses on those readmissions that are clinically related to the index admission and are potentially preventable by the IPF. The commenter also suggested that readmissions measures should be risk-adjusted to account for differences across patients in the likelihood of readmission, and stated that appropriate risk adjustment should include patient assessment data. Other commenters stated that a readmissions measure for the IPF setting may not be a true assessment of the quality of inpatient psychiatric care because IPF patients tend to exhibit characteristics that the available literature associates as risk factors for hospital readmissions. One commenter further stated that, while quality measures and care pathways aimed at improving medical care for heart attacks, heart failure, and pneumonia have been in place for more than a decade, psychiatric measures and care pathways for treating chronic psychiatric diseases are in their early stages of development, suggesting that a readmission to IPF care may not indicate anything meaningful about the quality and extent of care provided during an initial stay. In addition, we received a comment recommending that CMS consider a number of issues as it develops a readmissions measure for the Program. First, the commenter asked whether such a measure would include only Medicare patients or all IPF admissions because providers do not have access to the databases required to report or track readmissions across all payers. Second, the commenter expressed concern that there may be no relationship between a psychiatric hospital admission and a subsequent medical or surgical admission within 30 days, but that consumers will not have access to this level of information. Third, the commenter expressed concern that there are presently no published studies on the current readmission rate for IPFs. Fourth, the commenter expressed concern that there is no risk-adjustment proposed. Fifth, the commenter argued that there is currently no NQF endorsement of the measure being developed. Other commenters stated that a future readmissions measure should be limited to psychiatric readmission to the same facility. One commenter expressed support for a readmissions measure in future Program years, but recommended that CMS remove the unrelated acute medical admissions from the definition

of an unplanned 30-day IPF readmission because such a readmission is not a reflection on the quality of care provided at the index IPF admission. Another commenter recommended that, with regard to a potential readmissions measure, an exception should be made for dementia-related behavior disorders because these are by nature frequently repeating and heavily dependent on factors beyond the control of acute psychiatry.

In addition, we received several comments recommending that CMS engage the IPF technical expert panel for its guidance and advice on the challenges associated with implementing many of the measures under consideration for proposal for inclusion in future Program years. We also received comments recommending the following areas for further development and testing of potential measures: Readmission to the same IPF within 30 days of discharge; improved functioning or stabilization of functioning as measured through clinical assessment, patient self-assessment, or discharge to a lower level of care; receiving best-practices specific to the conditions noted in the treatment plan (for example, depression, bipolar, and schizophrenia), as well as acuity of illness; and scheduled appointment for aftercare within 7 days of discharge, controlling for urban/rural area and type of provider, at a minimum.

Lastly, one commenter recommended that CMS propose the adoption of Tobacco Use Treatment Management at Discharge measure (TOB–3; NQF # 1656) in future program years.

Response: We thank the commenters for their recommendations on potential measures and related issues for the IPFQR Program. We will take these recommendations into consideration as we continue to develop and propose measures for future program years.

7. Public Display and Review Requirements

Section 1886(s)(4)(E) of the Act requires the Secretary to establish procedures for making the data submitted under the IPFQR Program available to the public. The statute also requires that these procedures shall ensure that an IPF has the opportunity to review the data that is to be made public with respect to the IPF prior to the data being made public.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50897 through 50898), we adopted our proposal to change our policies to better align the IPFQR Program preview and display periods with those under the HIQR Program. For the FY 2014 payment determination and

subsequent years, we adopted our proposed policy to publicly display the submitted data on a CMS Web site in April of each calendar year following the start of the respective payment determination year. In other words, the public display period for the FY 2014

payment determination would be April 2014; the public display periods for the FY 2015 and FY 2016 payment determinations would be April 2015 and April 2016, respectively; and so forth. We also adopted our proposed policy that the preview period for the

FY 2014 payment determination and subsequent years be modified from September 20 through October 19 (78 FR 50898) to 30 days, approximately twelve weeks prior to the public display of the data. The table below sets out the public display timeline.

TABLE 15—PUBLIC DISPLAY TIMELINE

Payment determination (fiscal year)	Reporting period (calendar year)	Public display (calendar year)
2015	Q2 2013 (April 1, 2013–June 30, 2013) Q3 2013 (July 1, 2013–September 30, 2013). Q4 2013 (October 1, 2013–December 31, 2013).	April 2015.
2016	Q1 2014 (January 1, 2014–March 31, 2014) Q2 2014 (April 1, 2014–June 30, 2014). Q3 2014 (July 1, 2014–September 30, 2014). Q4 2014 (October 1, 2014–December 31, 2014).	April 2016.
2017	Q1 2015 (January 1, 2015–March 31, 2015) Q2 2015 (April 1, 2015–June 30, 2015). Q3 2015 (July 1, 2015–September 30, 2015). Q4 2015 (October 1, 2015–December 31, 2015).	April 2017.

Although we have listed the public display timeline only for the FY 2015 through FY 2017 payment determinations, we wish to clarify that this policy applies to the FY 2015 payment determination and subsequent years.

We did not propose any changes to these policies in the FY 2015 proposed rule. Therefore, we are finalizing these policies in this final rule.

8. Form, Manner, and Timing of Quality Data Submission

a. Procedural and Submission Requirements

Section 1886(s)(4)(C) of the Act requires that, for the FY 2014 payment determination and subsequent years, each IPF shall submit to the Secretary data on quality measures as specified by the Secretary. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary. As required by section 1886(s)(4)(A) of the Act, for any IPF that fails to submit quality data in accordance with section 1886(s)(4)(C) of the Act, the Secretary will reduce the annual update to a standard Federal rate for discharges occurring in such fiscal year by 2.0 percentage points. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53655 through 53656), we finalized a policy requiring that IPFs submit aggregate data on measures on an annual basis via

the Web-Based Measures Tool found in the IPF section on the QualityNet Web site. The complete data submission requirements, submission deadlines, and data submission mechanism, known as the Web-Based Measures Tool, are posted on the QualityNet Web site at: <http://www.qualitynet.org/>. The data input forms on the QualityNet Web site for submission require aggregate data for each separate quarter. Therefore, IPFs need to track and maintain quarterly records for their data. In that final rule, we also clarified that this policy applies to all subsequent years, unless and until we change our policy through future rulemaking.

To participate in the IPFQR Program, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53654 through 53655) and in the FY 2014 IPPS/LTCH PPS final rule (77 FR 50898 through 50899), we required IPFs to comply with certain procedural requirements. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (77 FR 50898 through 50899) for further details on specific procedural requirements.

We did not propose any changes to these policies in the FY 2015 proposed rule. Therefore, we are finalizing these policies in this final rule.

b. Reporting Periods and Submission Timeframes

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53655 through 53657), we

established reporting periods and submission timeframes for the FY 2014, FY 2015, and FY 2016 payment determinations, but we did not require any data validation approach. However, as we stated in that final rule, we encourage IPFs to use a validation method and conduct their own analysis. In that final rule, we also explained that the reporting periods for the FY 2014 and FY 2015 payment determinations were 6 and 9 months, respectively, to allow us to achieve a 12-month (calendar year) reporting period for the FY 2016 payment determination. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50901), we clarified that the policy we adopted for the FY 2016 payment determination also applies to the FY 2017 payment determination and subsequent years, unless we change it through rulemaking. We also indicated that the submission timeframe is between July 1 and August 15 of the calendar year in which the applicable payment determination year begins.

We did not propose any changes to this submission timeframe in 79 FR 26040, which we finalized in the FY 2014 IPPS/LTCH PPS final rule for all future payment determinations. IPFs will have the opportunity to review and correct data that they have submitted during the entirety of July 1 through August 15. We have summarized this information in the table below.

TABLE 16—QUALITY REPORTING PERIODS AND SUBMISSION TIMEFRAMES FOR THE FY 2015 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Payment determination (fiscal year)	Reporting period for services provided (calendar year)	Data submission timeframe
Quality Reporting Periods and Submission Timeframes for the FY 2015 Payment Determination and Subsequent Years		
FY 2015	Q2 2013 (April 1, 2013–June 30, 2013) Q3 2013 (July 1, 2013–September 30, 2013). Q4 2013 (October 1, 2013–December 31, 2013).	July 1, 2014–August 15, 2014.
FY 2016	Q1 2014 (January 1, 2014–March 31, 2014) Q2 2014 (April 1, 2014–June 30, 2014). Q3 2014 (July 1, 2014–September 30, 2014). Q4 2014 (October 1, 2014–December 31, 2014).	July 1, 2015–August 15, 2015.
FY 2017	Q1 2015 (January 1, 2015–March 31, 2015) Q2 2015 (April 1, 2015–June 30, 2015). Q3 2015 (July 1, 2015–September 30, 2015). Q4 2015 (October 1, 2015–December 31, 2015).	July 1, 2016–August 15, 2016.

We have adopted the timeframes discussed above for all future payment years of the program, and these timeframes will remain in place, unless and until we change them through future rulemaking. Therefore, our policy with respect to reporting timeframes is that the reporting period is the calendar year preceding the calendar year in which the payment determination year begins. The data submission timeframe is between July 1 and August 15 of the calendar year in which the applicable payment determination year begins. We will continue to provide charts with the specific reporting and data submission timeframes for future years as we approach those years.

We did not propose any changes to these policies in the FY 2015 proposed rule.

c. Population, Sampling, and Minimum Case Threshold

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53657 through 53658), for the FY 2014 payment determination and subsequent years, we finalized our proposed policy that participating IPFs must meet specific population, sample size, and minimum reporting case threshold requirements as specified in TJC's Specifications Manual. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 58901 through 58902). We are not proposing any changes to this policy. We refer participating IPFs to TJC's Specifications Manual (<https://manual.jointcommission.org/bin/view/Manual/WebHome>) for measure-specific population, sampling, and minimum case threshold requirements.

We did not propose any changes to these policies in the FY 2015 proposed

rule. Therefore, we are finalizing these policies in this final rule.

d. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658), we finalized our proposed DACA policy for the FY 2014 payment determination and subsequent years. We refer readers to that final rule for further details on DACA policies.

We are not changing the quarterly reporting periods or DACA deadline. Therefore, we will continue our adopted policy that the deadline for submission of the DACA form is no later than August 15 prior to the applicable IPFQR Program payment determination year. The table below summarizes these policies and timeframes.

TABLE 17—DACA SUBMISSION DEADLINE

Payment determination (fiscal year)	Reporting period for services provided (calendar year)	Submission timeframe	DACA deadline	Public display
2015	Q2 2013 (April 1, 2013–June 30, 2013) Q3 2013 (July 1, 2013–September 30, 2013). Q4 2013 (October 1, 2013–December 31, 2013).	July 1, 2014–August 15, 2014	August 15, 2014	April 2015.
2016	Q1 2014 (January 1, 2014–March 31, 2014) Q2 2014 (April 1, 2014–June 30, 2014). Q3 2014 (July 1, 2014–September 30, 2014). Q4 2014 (October 1, 2014–December 31, 2014).	July 1, 2015–August 15, 2015	August 15, 2015	April 2016.
2017	Q1 2015 (January 1, 2015–March 31, 2015) Q2 2015 (April 1, 2015–June 30, 2015). Q3 2015 (July 1, 2015–September 30, 2015). Q4 2015 (October 1, 2015–December 31, 2015).	July 1, 2016–August 15, 2016	August 15, 2016	April 2017.

We once again clarify that the DACA policies adopted in the FY 2013 IPPS/LTCH PPS final rule will continue to apply for the FY 2014 payment

determination and subsequent years, unless and until we change these policies through our rulemaking process.

We did not propose any changes to these policies in the FY 2015 proposed rule. Therefore, we are finalizing these policies in this final rule.

9. Reconsideration and Appeals Procedures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658 through 53659), we adopted a reconsideration process, later codified at 42 CFR 412.434, whereby IPFs can request a reconsideration of their payment update reduction in the event that an IPF believes that its annual payment update has been incorrectly reduced for failure to report quality data under the IPFQR Program. We refer readers to that final rule, as well as the FY 2014 IPPS/LTCH PPS final rule (78 FR 50903), for further details on the reconsideration process.

We did not propose any changes to these policies in the FY 2015 proposed rule. Therefore, we are finalizing these policies in this final rule.

10. Exceptions to Quality Reporting Requirements

In our experience with other quality reporting and performance programs, we have noted occasions where participants have been unable to submit required quality data due to extraordinary circumstances that are not within their control (for example, natural disasters). It is our goal to avoid penalizing IPFs in these circumstances or unduly increasing their burden during these times. Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53659 through 53660), we adopted a policy where, for the FY 2014 payment determination and subsequent years, IPFs may request, and we may grant, an exception with respect to the reporting of required quality data where extraordinary circumstances beyond the control of the IPF may warrant. We wish to clarify that use of the term “exception” in this final rule is synonymous with the term “waiver” as used in previous rules. We are in the process of revising the Extraordinary Circumstances/Disaster Extension or Waiver Request form (CMS–10432), approved under OMB control number 0938–1171. Revisions to the form are being addressed in the FY 2015 Inpatient Prospective Payment System (IPPS) rule (RIN 0938–AS11; CMS–1607–P) in the section entitled “Hospital IQR Program Extraordinary Circumstances Extensions or Exemptions”. These efforts will work to facilitate alignment across CMS quality reporting programs.

When an exception is granted, IPFs will not incur payment reductions for failure to comply with IPFQR Program requirements. This process does not preclude us from granting exceptions, including extensions, to IPFs that have not requested them, should we

determine that an extraordinary circumstance affects an entire region or locale. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53659 through 53660), as well as the FY 2014 IPPS/LTCH PPS final rule (78 FR 50903), for further details on this process. We are not changing this process.

In the FY 2015 proposed rule (78 FR 26072 through 26073), we proposed to add an Extraordinary Circumstances Exception to the IPFQR Program, effective for the FY 2016 payment determination and subsequent years, to align with similar exceptions provided for in other CMS quality reporting programs. Under this exception, we may grant a waiver or extension to IPFs if we determine that a systemic problem with one of our data collection systems directly affects the ability of the IPFs to submit data. Because we do not anticipate that these types of systemic errors will occur often, we do not anticipate granting a waiver or extension on this basis frequently. If we make the determination to grant a waiver or extension, we will communicate this decision through routine communication channels to IPFs, vendors, and quality improvement organizations (QIOs) by means of, for example, memoranda, emails, and notices on the QualityNet Web site. Public comments and responses to comments on the exceptions to quality reporting requirements are summarized below.

Comment: Some commenters expressed support for inclusion of an Extraordinary Circumstances Exception in the Program.

Response: We thank the commenters for their support.

Final Rule Action: After consideration of the public comments, we are finalizing the Extraordinary Circumstances Exception as proposed for the FY 2016 payment determination and subsequent years.

IX. Provisions of the Final Regulations

This final rule essentially incorporates the provisions of the proposed rule set forth in the FY 2015 IPF PPS proposed rule (79 FR 26040), in which we proposed to update the IPF PPS for FY 2015 applicable to IPF discharges occurring during the FY beginning October 1, 2014 through September 30, 2015. In addition, we proposed to update the COLA adjustment factors for IPFs located in Alaska and Hawaii using the approach finalized in the FY 2014 IPPS final rule (FR 50985 through 50987). This final rule will also address implementation of ICD–10–CM and ICD–9–PCS codes and

finalize new quality measures and quality reporting requirements under the quality reporting program.

X. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency
- The accuracy of our estimate of the information collection burden
- The quality, utility, and clarity of the information to be collected
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the May 6, 2014 (79 FR 26040) proposed rule, we solicited public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs). However, we did not receive any public comments on these ICRs and are adopting the policies as proposed.

A. ICRs Regarding the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

The following sets out the estimated burden (hours and cost) for inpatient psychiatric facilities (IPFs) to comply with the reporting requirements under section VIII of this rule.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53644), we finalized policies implementing the IPFQR Program. The Program implements the statutory requirements of section 1886(s)(4) of the Social Security Act, as added by sections 3401(f) and 10322(a) of the Affordable Care Act. One program priority is to help achieve better health and better health care for individuals through the collection of valid, reliable, and relevant measures of quality health care data. The data are publicly available for use in improving health care quality which, in turn, works to further Program goals. IPFs can use this quality data for many purposes, including in their risk management programs, patient safety and quality improvement initiatives, and research

and development of mental health programs, among others.

As clarified throughout the FY 2014 IPPS/LTCH PPS final rule (78 FR 50887), policies finalized in prior rules will apply to FY 2015, unless and until we change them through future rulemaking. The burden on IPFs includes the time used for chart abstraction and for personnel training on the collection of chart-abstracted data, the aggregation of data, and training for the submission of aggregate-level data through QualityNet. We note that, beginning in the FY 2016 payment determination, we have adopted the Assessment of Patient Experience of Care measure, thereby removing the request for voluntary information adopted in the FY 2014 IPPS/LTCH PPS final rule.

Based on current participation rates, we estimate that there will be approximately 574 fewer IPF facilities, or 1,626 facilities nationwide eligible to participate in the IPFQR Program. Based on previous measure data submission, we further estimate that the average

facility submits measure data on 556 cases per year. In total, this calculates to 904,056 cases (aggregate) per year.

In section V of this preamble, we are finalizing our proposals that, for the FY 2016 payment determination and subsequent years, IPFs must submit data on the following new measures: Assessment of Patient Experience of Care, and Use of an Electronic Health Record. Because both of these measures require only an annual acknowledgement, we anticipate a negligible additional burden on IPFs.

In the same section of this preamble, we are finalizing our proposals that, for the FY 2017 payment determination and subsequent years, IPFs must submit aggregate data on the following new measures: Influenza Immunization (IMM-2), Influenza Vaccination Coverage Among Healthcare Personnel, Tobacco Use Screening (TOB-1), and Tobacco Use Treatment Provided or Offered (TOB-2) and Tobacco Use Treatment (TOB-2a).

We estimate that the average time spent for chart abstraction per patient for each of these measures is

approximately 15 minutes. Assuming an approximately uniform sampling methodology, we estimate (based on prior Program data) that the annual burden for reporting the IMM-2 measure is 139 hours per year of annual effort per facility (556×0.25). This same calculation also applies to the TOB-1, and TOB-2 and TOB-2a measures. The Influenza Vaccination Coverage Among Healthcare Personnel measure does not allow sampling; therefore, we anticipate that the average facility would be required to abstract approximately 40 healthcare personnel, totaling an annual effort per facility of 10 hours (40×0.25). We anticipate no measurable burden for the Inpatient Psychiatric Facility Routinely Assesses Patient Experience of Care measure and the Use of an Electronic Health Record measure because both require only attestation.

In total, we estimate an additional 427 hours of annual effort per facility for the FY 2017 payment determination and subsequent years. The following table summarizes the estimated hours (per facility) for each measure.

TABLE 18—ESTIMATED ANNUAL EFFORT PER FACILITY

Measure	Estimated cases (per facility)	Effort (per case)	Annual effort (per facility)
Assessment of Patient Experience of Care	*0	n/a *	*0
Use of an Electronic Health Record	*0;	a *	*0
IMM-2	556	¼ hour	139
Influenza Vaccination Coverage Among Healthcare Personnel	40	¼ hour	10
TOB-1	556	¼ hour	139
TOB-2, TOB-2a	556	¼ hour	139
Total			427

* New non-measurable attestation burden.

The Bureau of Labor Statistics wage estimate for health care workers that are known to engage in chart abstraction is \$31.71/hour. To account for overhead and fringe benefits we have doubled this estimate to \$63.42/hour. Considering the 427 hours of annual effort (per facility) for the FY 2017 payment determination and subsequent years, the annual cost is approximately \$27,080.34 (63.42×427). Across all 1,626 IPFs, the aggregate total is \$44,032,632.84 ($1,626 \times 27,080.34$).

The estimated burden for training personnel for data collection and submission for current and future measures is 2 hours per facility. The cost for this training, based on an hourly rate of \$63.42, is \$126.84 training costs

for each IPF (63.42×2), which totals \$206,241.84 for all facilities ($1,626 \times 126.84$).

Using an estimated 1,626 IPFs nationwide eligible for participation in the IPFQR Program, we estimate that the annual hourly burden for the collection, submission, and training of personnel for submitting all quality measures is approximately 429 hours (per IPF) or 697,554 (aggregate) per year. The all-inclusive measure cost for each facility is approximately \$27,207.18 ($27,080.34 + 126.84$) and for all facilities we estimate a cost of \$44,238,874.68 ($44,032,632.84 + 206,241.84$).

In section V of this preamble, for the FY 2017 payment determination, we finalized our proposal that IPFs must submit to CMS aggregate population

counts for Medicare and non-Medicare discharges by age group, diagnostic group, and quarter, and sample size counts for measures for which sampling is performed (as is allowed for in HBIPS-4 through -7, and SUB-1). We estimate that it will take each facility approximately 2.5 hours to comply with this requirement. The burden across all 1,626 IPFs calculates to 4,065 hours annually ($2.5 \times 1,626$) at a total of \$257,802.30 ($4,065 \times 63.42$) or \$158.55 per IPF (2.5×63.42).

The following tables set out the total estimated burden that IPFs will incur to comply with the reporting requirements for both measure and non-measure data for the FY 2016 and FY 2017 payment determinations.

TABLE 19—SUMMARY OF BURDEN ESTIMATES (OCN 0938–1171, CMS–10432) FOR THE FY 2016 PAYMENT DETERMINATION

Fiscal year 2016	Number of measures	Respondents	Facility burden (hours)	Total annual burden (hours)	Labor cost of reporting (\$/hr)	Total cost (\$)
From this FY 2015 rule	2 (attestation only)	1,626	0	0	0	0
	training	1,626	0	0	0	0
Total		1,626	0	0	0	0

TABLE 20—SUMMARY OF BURDEN ESTIMATES (OCN 0938–1171, CMS–10432) FOR THE FY 2017 PAYMENT DETERMINATION

Fiscal year 2017	Number of measures	Respondents	Facility burden (hours)	Total annual burden (hours)	Labor cost of reporting (\$/hr)	Total cost (\$)
From this FY 2015 rule	4	1,626	427 (139 × 3 + 10)	694,302	63.42	44,032,632.84
	2 (attestation only)			0		
	training		2	3,252		206,241.84
Subtotal		1,626	429	697,554	63.42	44,238,874.68
From this FY 2015 rule	Non-measure data	1,626	2.50	4,065	63.42	257,802.30
Total		1,626	431.50	701,619	63.42	44,496,676.98

We are not changing any of the administrative, reporting, or submission requirements for the measures previously finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53654 through 53657) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50898 through 50903), except that we are removing the Request for Voluntary Information—IPF Assessment of Patient Experience of Care section because of the Assessment of Patient Experience of Care measure.

B. FY 2014 and FY 2015 Burden Adjustments (OCN 0938–1171, CMS–10432)

In the FY 2014 final rule (78 FR 50964), we estimated that the annual hourly burden per IPF for the collection, submission, and training of personnel for submitting all quality measures was approximately 761 hours. This figure represented an estimate for all measures, both previously and newly finalized, in the Program. We further stated that because we were unable to estimate how many IPFs will participate, we could not estimate the aggregate impact.

Because the estimates we present herein, including the estimated annual burden of 431.5 hours per IPF, represent estimates only for measure and non-measure data collection and submission requirements, an accurate comparison with estimates presented in the FY 2014 final rule is not possible.

C. ICRs Regarding the Hospital and Health Care Complex Cost Report (CMS–2552–10)

This final rule would not impose any new or revised collection of information requirements associated with CMS–2552–10 (as discussed under preamble section IV.B.). Consequently, the cost report does not require additional OMB review under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The report's information collection requirements and burden estimates have been approved by OMB under OCN 0938–0052.

D. ICRs Regarding Exceptions to Quality Reporting Requirements

As discussed in section VII.10, we are in the process of revising the Extraordinary Circumstances/Disaster Extension or Waiver Request form, currently approved under OMB control number 0938–1171. Revisions to the form are being addressed in the FY 2015 Inpatient Prospective Payment System rule (RIN 0938–AS11, CMS–1607–F). In that rule we update the form's instructions and simplify the form so that a hospital or facility may apply for an extension for all applicable quality reporting programs at the same time.

E. Submission of PRA-Related Comments

We have submitted a copy of this rule to OMB for its review of the rule's information collection and

recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

When commenting on the stated information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

Mail: OMB, Office of Information and Regulatory Affairs Attention: CMS Desk Officer
Fax: (202) 395–5806 OR
Email: OIRA_submission@omb.eop.gov.

PRA-related comments must be received on/by September 2, 2014.

XI. Comments Beyond the Scope of the Final Rule

In response to the proposed rule, a few commenters chose to raise issues that are beyond the scope of our proposals. In this final rule, we are not summarizing or responding to those comments in this document.

XII. Regulatory Impact Analysis

A. Statement of Need

This final rule updates the prospective payment rates for Medicare inpatient hospital services provided by IPFs for discharges occurring during the FY beginning October 1, 2014, through September 30, 2015. We are applying the FY 2008-based RPL market basket increase of 2.9 percent, less the productivity adjustment of 0.5

percentage point as required by section 1886(s)(2)(A)(i) of the Act, and less the 0.3 percentage point required by sections 1886(s)(2)(A)(ii) and 1886(s)(3)(C) of the Act. In this final rule, we also address the implementation of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM/PCS) for the IPF prospective payment system, and describe new quality reporting requirements for the IPFQR Program.

B. Overall Impact

We have examined the impact of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub.L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This final rule is designated as economically “significant” under section 3(f)(1) of Executive Order 12866.

We estimate that the total impact of these changes for FY 2015 payments compared to FY 2014 payments will be a net increase of approximately \$120 million. This reflects a \$100 million increase from the update to the payment rates, as well as a \$20 million increase as a result of the update to the outlier threshold amount. Outlier payments are estimated to increase from 1.6 percent in FY 2014 to 2.0 percent in FY 2015.

The RFA requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most IPFs and most other providers and suppliers are small entities, either by nonprofit status or having revenues of \$7 million to \$35.5 million or less in any 1 year,

depending on industry classification (for details, refer to the SBA Small Business Size Standards found at http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf), or being nonprofit organizations that are not dominant in their markets.

Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IPFs or the proportion of IPFs’ revenue derived from Medicare payments. Therefore, we assume that all IPFs are considered small entities. The Department of Health and Human Services generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA.

As shown in Table 21, we estimate that the overall revenue impact of this proposed rule on all IPFs is to increase Medicare payments by approximately 2.5 percent. As a result, since the estimated impact of this final rule is a net increase in revenue across all categories of IPFs, the Secretary has determined that this final rule will have a positive revenue impact on a substantial number of small entities. MACs are not considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. As discussed in detail below, the rates and policies set forth in this final rule will not have an adverse impact on the rural hospitals based on the data of the 309 rural units and 75 rural hospitals in our database of 1,626 IPFs for which data were available. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately \$141 million. This final rule will not impose spending costs on state, local, or tribal governments in the aggregate, or by the private sector, of \$141 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. As stated above, this final rule will not have a substantial effect on state and local governments.

C. Anticipated Effects

We discuss the historical background of the IPF PPS and the impact of this final rule on the Federal Medicare budget and on IPFs.

1. Budgetary Impact

As discussed in the November 2004 and May 2006 IPF PPS final rules, we applied a budget neutrality factor to the Federal per diem and ECT base rates to ensure that total estimated payments under the IPF PPS in the implementation period would equal the amount that would have been paid if the IPF PPS had not been implemented. The budget neutrality factor includes the following components: Outlier adjustment, stop-loss adjustment, and the behavioral offset. As discussed in the May 2008 IPF PPS notice (73 FR 25711), the stop-loss adjustment is no longer applicable under the IPF PPS.

In accordance with § 412.424(c)(3)(ii), we indicated that we will evaluate the accuracy of the budget neutrality adjustment within the first 5 years after implementation of the payment system. We may make a one-time prospective adjustment to the Federal per diem and ECT base rates to account for differences between the historical data on cost-based TEFRA payments (the basis of the budget neutrality adjustment) and estimates of TEFRA payments based on actual data from the first year of the IPF PPS. As part of that process, we will reassess the accuracy of all of the factors impacting budget neutrality. In addition, as discussed in section VII.C.1 of this final rule, we are using the wage index and labor-related share in a budget neutral manner by applying a wage index budget neutrality factor to the Federal per diem and ECT base rates. Therefore, the budgetary impact to the Medicare program of this final rule will be due to the market basket update for FY 2015 of 2.9 percent (see section V.B. of this final rule) less the productivity adjustment of 0.5 percentage point required by section 1886 (s)(2)(A)(i) of the Act, less the “other adjustment” of 0.3 percentage point under sections 1886(s)(2)(A)(ii) and 1886 (s)(3)(C) of the Act, and the

update to the outlier fixed dollar loss threshold amount.

We estimate that the FY 2015 impact will be a net increase of \$120 million in payments to IPF providers. This reflects an estimated \$100 million increase from the update to the payment rates and a \$20 million increase due to the update to the outlier threshold amount to increase outlier payments from approximately 1.6 percent in FY 2014 to 2.0 percent in FY 2015. This estimate does not include the implementation of the required 2 percentage point reduction of the market basket increase factor for any IPF that fails to meet the IPF quality reporting requirements (as discussed in section 4 below).

2. Impact on Providers

To understand the impact of the changes to the IPF PPS on providers, discussed in this final rule, it is necessary to compare estimated payments under the IPF PPS rates and factors for FY 2015 versus those under FY 2014. The estimated payments for FY 2014 and FY 2015 will be 100 percent of the IPF PPS payment, since the transition period has ended and stop-loss payments are no longer paid.

We determined the percent change of estimated FY 2015 IPF PPS payments to FY 2014 IPF PPS payments for each category of IPFs. In addition, for each category of IPFs, we have included the estimated percent change in payments resulting from the update to the outlier fixed dollar loss threshold amount, the labor-related share and wage index changes for the FY 2015 IPF PPS, and the market basket update for FY 2015, as adjusted by the productivity adjustment according to section 1886(s)(2)(A)(i), and the “other adjustment” according to sections 1886(s)(2)(A)(ii) and 1886(s)(3)(C) of the Act.

To illustrate the impacts of the FY 2015 changes in this final rule, our analysis begins with a FY 2014 baseline simulation model based on FY 2013 IPF payments inflated to the midpoint of FY 2014 using IHS Global Insight Inc.’s most recent forecast of the market basket update (see section IV.C. of this final rule); the estimated outlier payments in FY 2014; the CBSA designations for IPFs based on OMB’s MSA definitions after June 2003; the FY 2013 pre-floor, pre-reclassified hospital wage index; the FY 2014 labor-related share; and the FY

2014 percentage amount of the rural adjustment. During the simulation, the total estimated outlier payments are maintained at 2 percent of total IPF PPS payments.

Each of the following changes is added incrementally to this baseline model in order for us to isolate the effects of each change:

- The update to the outlier fixed dollar loss threshold amount.
- The FY 2014 pre-floor, pre-reclassified hospital wage index and FY 2015 labor-related share.
- The market basket update for FY 2015 of 2.9 percent less the productivity adjustment of 0.5 percentage point reduction in accordance with section 1886(s)(2)(A)(i) of the Act and less the “other adjustment” of 0.3 percentage point in accordance with sections 1886(s)(2)(A)(ii) and 1886(s)(3)(C) of the Act.

Our final comparison illustrates the percent change in payments from FY 2014 (that is, October 1, 2013, to September 30, 2014) to FY 2015 (that is, October 1, 2014, to September 30, 2015) including all the changes in this final rule.

TABLE 21—IPF IMPACT TABLE FOR FY 2015

[Projected impacts (% change in columns 3–6)]

Facility by type	Number of facilities	Outlier	CBSA wage index & labor share	Adjusted market basket update ¹	Total percent change ²
(1)	(2)	(3)	(4)	(5)	(6)
All Facilities:	1,626	0.4	0.0	2.1	2.5
Total Urban	1,242	0.4	0.0	2.1	2.5
Total Rural	384	0.3	–0.1	2.1	2.3
Urban unit	827	0.6	0.1	2.1	2.7
Urban hospital	415	0.2	0.0	2.1	2.2
Rural unit	309	0.4	–0.1	2.1	2.4
Rural hospital	75	0.2	–0.3	2.1	2.0
By Type of Ownership:					
Freestanding IPFs:					
Urban Psychiatric Hospitals:					
Government	129	0.4	–0.1	2.1	2.4
Non-Profit	99	0.3	0.2	2.1	2.6
For-Profit	187	0.0	–0.2	2.1	2.0
Rural Psychiatric Hospitals:					
Government	37	0.3	0.2	2.1	2.7
Non-Profit	13	0.2	–0.1	2.1	2.2
For-Profit	25	0.0	–0.7	2.1	1.4
IPF Units:					
Urban:					
Government	125	0.8	0.1	2.1	3.0
Non-Profit	546	0.6	0.1	2.1	2.8
For-Profit	156	0.3	–0.1	2.1	2.3
Rural:					
Government	76	0.3	–0.1	2.1	2.3
Non-Profit	168	0.4	–0.1	2.1	2.4
For-Profit	65	0.4	0.0	2.1	2.6
By Teaching Status:					
Non-teaching	1,426	0.3	0.0	2.1	2.4
Less than 10% interns and residents to beds	109	0.5	0.2	2.1	2.8
10% to 30% interns and residents to beds	65	0.8	–0.1	2.1	2.9
More than 30% interns and residents to beds	26	1.0	0.5	2.1	3.7
By Region:					

TABLE 21—IPF IMPACT TABLE FOR FY 2015—Continued
[Projected impacts (% change in columns 3–6)]

Facility by type (1)	Number of facilities (2)	Outlier (3)	CBSA wage index & labor share (4)	Adjusted market basket update ¹ (5)	Total percent change ² (6)
New England	109	0.6	0.1	2.1	2.8
Mid-Atlantic	250	0.4	0.6	2.1	3.1
South Atlantic	235	0.3	−0.3	2.1	2.1
East North Central	260	0.4	−0.2	2.1	2.3
East South Central	165	0.3	−0.3	2.1	2.2
West North Central	144	0.4	−0.3	2.1	2.3
West South Central	238	0.2	−0.4	2.1	1.9
Mountain	103	0.3	−0.3	2.1	2.1
Pacific	122	0.6	0.9	2.1	3.7
By Bed Size:					
Psychiatric Hospitals:					
Beds: 0–24	88	0.1	−0.3	2.1	2.0
Beds: 25–49	67	0.1	−0.1	2.1	2.1
Beds: 50–75	87	0.2	−0.1	2.1	2.2
Beds: 76 + ...	248	0.2	0.0	2.1	2.2
Psychiatric Units:					
Beds: 0–24	677	0.6	0.0	2.1	2.7
Beds: 25–49	298	0.5	−0.1	2.1	2.6
Beds: 50–75	102	0.4	0.0	2.1	2.6
Beds: 76 + ...	59	0.6	0.4	2.1	3.1

¹ This column reflects the payment update impact of the RPL market basket update for FY 2015 of 2.9 percent, a 0.5 percentage point reduction for the productivity adjustment as required by section 1886(s)(2)(A)(i) of the Act, and a 0.3 percentage point reduction in accordance with sections 1886(s)(2)(A)(ii) and 1886(s)(3)(C) of the Act.

² Percent changes in estimated payments from FY 2014 to FY 2015 include all of the changes presented in this proposed rule. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

3. Results

Table 21 above displays the results of our analysis. The table groups IPFs into the categories listed below based on characteristics provided in the Provider of Services (POS) file, the IPF provider specific file, and cost report data from HCRIS:

- Facility Type
- Location
- Teaching Status Adjustment
- Census Region
- Size

The top row of the table shows the overall impact on the 1,626 IPFs included in this analysis.

In column 3, we present the effects of the update to the outlier fixed dollar loss threshold amount. We estimate that IPF outlier payments as a percentage of total IPF payments are 1.6 percent in FY 2014. Thus, we are adjusting the outlier threshold amount in this final rule to set total estimated outlier payments equal to 2 percent of total payments in FY 2015. The estimated change in total IPF payments for FY 2015, therefore, includes an approximate 0.4 percent increase in payments because the outlier portion of total payments is expected to increase from approximately 1.6 percent to 2 percent.

The overall impact of this outlier adjustment update (as shown in column 3 of table 21), across all hospital groups,

is to increase total estimated payments to IPFs by 0.4 percent. We do not estimate that any group of IPFs will experience a decrease in payments from this update. The largest increase in payments is estimated to reflect a 1 percent increase in payments for IPFs located in teaching hospitals with an intern and resident ADC ratio greater than 30 percent.

In column 4, we present the effects of the budget-neutral update to the labor-related share and the wage index adjustment under the CBSA geographic area definitions announced by OMB in June 2003. This is a comparison of the simulated FY 2015 payments under the FY 2014 hospital wage index under CBSA classification and associated labor-related share to the simulated FY 2014 payments under the FY 2013 hospital wage index under CBSA classifications and associated labor-related share. We note that there is no projected change in aggregate payments to IPFs, as indicated in the first row of column 4. However, there will be small distributional effects among different categories of IPFs. For example, we estimate the largest increase in payments to be a 0.9 percent increase for IPFs in the Pacific region and the largest decrease in payments to be a 0.7 percent decrease for rural for-profit IPFs.

Column 5 shows the estimated effect of the update to the IPF PPS payment rates, which includes a 2.9 percent market basket update less the productivity adjustment of 0.5 percentage point in accordance with section 1886(s)(2)(A)(i), and less the 0.3 percentage point in accordance with section 1886(s)(2)(A)(ii) and 1886(s)(3)(C).

Column 6 compares our estimates of the total changes reflected in this final rule for FY 2015, to our payments for FY 2014 (without these changes). This column reflects all FY 2015 changes relative to FY 2014. The average estimated increase for all IPFs is approximately 2.5 percent. This estimated net increase includes the effects of the 2.9 percent market basket update adjusted by the productivity adjustment of minus 0.5 percentage point, as required by section 1886(s)(2)(A)(i) of the Act and the “other adjustment” of minus 0.3 percentage point, as required by sections 1886(s)(2)(A)(ii) and 1886(s)(3)(C) of the Act. It also includes the overall estimated 0.4 percent increase in payments from the update to the outlier fixed dollar loss threshold amount. Since we are making the updates to the IPF labor-related share and wage index in a budget-neutral manner, they will not affect total

estimated IPF payments in the aggregate. However, they will affect the estimated distribution of payments among providers.

Overall, no IPFs are estimated to experience a net decrease in payments as a result of the updates in this final rule. IPFs in urban areas will experience a 2.5 percent increase and IPFs in rural areas will experience a 2.3 percent increase. The largest payment increase is estimated at 3.7 percent for IPFs located in teaching hospitals with an intern and resident ADC ratio greater than 30 percent and IPFs in the Pacific region. This is due to the larger than average positive effect of the CBSA wage index and labor-related share updates and the higher volume of outlier payments for IPFs in these categories.

4. Effects of Updates to the IPF QRP

As discussed in section V.B. of this final rule and in accordance with section 1886(s)(4)(A)(ii) of the Act, we will implement a 2 percentage point reduction in the FY 2015 increase factor for IPFs that have failed to report the required quality reporting data to us during the most recent IPF quality reporting period. In section V.B. of this final rule, we discuss how the 2 percentage point reduction will be applied. Only a few IPFs received the 2 percentage point reduction in the FY 2014 increase factor for failure to meet program requirements, and we will anticipate that even fewer IPFs would receive the reduction for FY 2015 as IPFs become more familiar with the requirements. Thus, we estimate that this policy will have a negligible impact on overall IPF payments for FY 2015.

For the FY 2016 payment determination, we estimate no additional burden on IPFs as a result of changes in reporting requirements. For

the FY 2017 payment determination, we estimate an additional annual burden across all 1,626 IPFs of 701,619 hours, with a total Program cost of \$44,496,677. This estimate includes an estimated 3,252 hours annually for training, at an estimated annual cost of \$206,241. It also includes an estimated 4,065 hours annually, at an estimated annual cost of \$257,802, for IPFs to submit to CMS aggregate population counts for Medicare and non-Medicare discharges by age group, diagnostic group, and quarter, and sample size counts for measures for which sampling is performed. Further discussion of these figures can be found in section IX.

For the FY 2017 payment determination, the applicable reporting period is calendar year (CY) 2015. Assuming that reporting costs are uniformly distributed across the year, three-quarters of those costs would have been incurred in FY 2015, which ends on September 30, 2015. Therefore, the estimated FY 2015 burden for IPFs will be three-quarters of \$44,496,677, or approximately \$33,372,508.

We intend to closely monitor the effects of this new quality reporting program on IPF providers and help facilitate successful reporting outcomes through ongoing stakeholder education, national trainings, and a technical help desk.

5. Effect on Beneficiaries

Under the IPF PPS, IPFs will receive payment based on the average resources consumed by patients for each day. We do not expect changes in the quality of care or access to services for Medicare beneficiaries under the FY 2015 IPF PPS but we continue to expect that paying prospectively for IPF services would enhance the efficiency of the Medicare program.

D. Alternatives Considered

The statute does not specify an update strategy for the IPF PPS and is broadly written to give the Secretary discretion in establishing an update methodology. Therefore, we are updating the IPF PPS using the methodology published in the November 2004 IPF PPS final rule. No alternative policy options were considered in this final rule since this final rule simply provides an update to the rates for FY 2015 and transition ICD-9-CM codes to ICD-10-CM codes. Additionally, for the IPFQR Program, alternatives were not considered because the Program, as designed, best achieves quality reporting goals for the inpatient psychiatric care setting, while minimizing associated reporting burdens on IPFs. Lastly, sections VIII.1. and VIII.4. discuss other benefits and objectives of the Program.

E. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4), in Table 22 below, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. The costs for data submission presented in Table 22 are calculated in section IX, which also discusses the benefits of data collection. This table provides our best estimate of the increase in Medicare payments under the IPF PPS as a result of the changes presented in this final rule and based on the data for 1,626 IPFs in our database. Furthermore, we present the estimated costs associated with updating the IPFQR program. The increases in Medicare payments are classified as Federal transfers to IPF Medicare providers.

TABLE 22—ACCOUNTING STATEMENT—CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
Change in Estimated Transfers from FY 2014 IPF PPS to FY 2015 IPF PPS	
Annualized Monetized Transfers	\$120 million.
From Whom to Whom?	Federal Government to IPF Medicare providers.
FY 2015 Costs to updating the Quality Reporting Program for IPFs	
Category	Costs
Annualized Monetized Costs for IPFs to Submit Data (Quality Reporting Program).	33,372,508.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

Dated: July 24, 2014

Marilyn Tavenner,
Administrator, Centers for Medicare & Medicaid Services.

Approved: July 30, 2014.

Sylvia M. Burwell,
Secretary.

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

Addendum A—Rate and Adjustment Factors

PER DIEM RATE

Federal Per Diem Base Rate	\$728.31
Labor Share (0.69294)	504.68
Non-Labor Share (0.30706)	223.63

PER DIEM RATE APPLYING THE 2 PERCENTAGE POINT REDUCTION

Federal Per Diem Base Rate	\$714.05

FACILITY ADJUSTMENTS

Rural Adjustment Factor	1.17.
Teaching Adjustment Factor	0.5150.
Wage Index	Pre-reclass Hospital Wage Index (FY2014).

COST OF LIVING ADJUSTMENTS (COLAS)

Area	Cost of living adjustment factor
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23
Rest of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.19
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

PATIENT ADJUSTMENTS

ECT—Per Treatment	\$313.55

PATIENT ADJUSTMENTS—Continued

ECT—Per Treatment Applying the 2 Percentage Point Reduction	307.41

VARIABLE PER DIEM ADJUSTMENTS

	Adjustment factor
Day 1—Facility Without a Qualifying Emergency Department	1.19
Day 1—Facility With a Qualifying Emergency Department	1.31
Day 2	1.12
Day 3	1.08
Day 4	1.05
Day 5	1.04
Day 6	1.02
Day 7	1.01
Day 8	1.01
Day 9	1.00
Day 10	1.00
Day 11	0.99
Day 12	0.99
Day 13	0.99
Day 14	0.99

VARIABLE PER DIEM ADJUSTMENTS—Continued

	Adjustment factor
Day 15	0.98
Day 16	0.97
Day 17	0.97
Day 18	0.96
Day 19	0.95
Day 20	0.95
Day 21	0.95
After Day 21	0.92

AGE ADJUSTMENTS

Age (in years)	Adjustment factor
Under 45	1.00
45 and under 50	1.01
50 and under 55	1.02
55 and under 60	1.04
60 and under 65	1.07
65 and under 70	1.10
70 and under 75	1.13
75 and under 80	1.15
80 and over	1.17

DRG ADJUSTMENTS

MS-DRG	MS-DRG descriptions	Adjustment factor
056	Degenerative nervous system disorders w MCC	1.05
057	Degenerative nervous system disorders w/o MCC	
080	Nontraumatic stupor & coma w MCC	1.07
081	Nontraumatic stupor & coma w/o MCC	
876	O.R. procedure w principal diagnoses of mental illness	1.22
880	Acute adjustment reaction & psychosocial dysfunction	1.05
881	Depressive neuroses	0.99
882	Neuroses except depressive	1.02
883	Disorders of personality & impulse control	1.02
884	Organic disturbances & mental retardation	1.03
885	Psychoses	1.00
886	Behavioral & developmental disorders	0.99
887	Other mental disorder diagnoses	0.92
894	Alcohol/drug abuse or dependence, left AMA	0.97
895	Alcohol/drug abuse or dependence w rehabilitation therapy	1.02
896	Alcohol/drug abuse or dependence w/o rehabilitation therapy w MCC	0.88

DRG ADJUSTMENTS—Continued

MS-DRG	MS-DRG descriptions	Adjustment factor
897	Alcohol/drug abuse or dependence w/o rehabilitation therapy w/o MCC	

COMORBIDITY ADJUSTMENTS

Comorbidity	Adjustment factor
Developmental Disabilities	1.04
Coagulation Factor Deficit	1.13
Tracheostomy	1.06
Eating and Conduct Disorders	1.12
Infectious Diseases	1.07
Renal Failure, Acute	1.11
Renal Failure, Chronic	1.11
Oncology Treatment	1.07
Uncontrolled Diabetes Mellitus	1.05
Severe Protein Malnutrition	1.13
Drug/Alcohol Induced Mental Disorders	1.03
Cardiac Conditions	1.11
Gangrene	1.10
Chronic Obstructive Pulmonary Disease	1.12
Artificial Openings—Digestive & Urinary	1.08
Severe Musculoskeletal & Connective Tissue Diseases	1.09
Poisoning	1.11

Addendum B—FY 2015 CBSA Wage Index Tables

In this addendum, we provide the wage index tables referred to in the preamble to

this final rule. The tables presented below are as follows:

Table 1—FY 2015 Wage Index For Urban Areas Based on CBSA Labor Market Areas.

Table 2—FY 2015 Wage Index Based On CBSA Labor Market Areas For Rural Areas.

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS

CBSA Code	Urban area (constituent counties)	Wage index
10180	Abilene, TX	0.8225
	Callahan County, TX.	
	Jones County, TX.	
	Taylor County, TX.	
10380	Aguadilla-Isabela-San Sebastián, PR	0.3647
	Aguada Municipio, PR.	
	Aguadilla Municipio, PR.	
	Añasco Municipio, PR.	
	Isabela Municipio, PR.	
	Lares Municipio, PR.	
	Moca Municipio, PR.	
	Rincón Municipio, PR.	
	San Sebastián Municipio, PR.	
10420	Akron, OH	0.8521
	Portage County, OH.	
	Summit County, OH.	
10500	Albany, GA	0.8713
	Baker County, GA.	
	Dougherty County, GA.	
	Lee County, GA.	
	Terrell County, GA.	
	Worth County, GA.	
10580	Albany-Schenectady-Troy, NY	0.8600
	Albany County, NY.	
	Rensselaer County, NY.	
	Saratoga County, NY.	
	Schenectady County, NY.	
	Schoharie County, NY.	
10740	Albuquerque, NM	0.9663
	Bernalillo County, NM.	
	Sandoval County, NM.	
	Torrance County, NM.	
	Valencia County, NM.	

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
10780	Alexandria, LA	0.7788
	Grant Parish, LA.	
	Rapides Parish, LA.	
10900	Allentown-Bethlehem-Easton, PA-NJ	0.9215
	Warren County, NJ.	
	Carbon County, PA.	
	Lehigh County, PA.	
	Northampton County, PA.	
11020	Altoona, PA	0.9101
	Blair County, PA.	
11100	Amarillo, TX	0.8302
	Armstrong County, TX.	
	Carson County, TX.	
	Potter County, TX.	
	Randall County, TX.	
11180	Ames, IA	0.9425
	Story County, IA.	
11260	Anchorage, AK	1.2221
	Anchorage Municipality, AK.	
	Matanuska-Susitna Borough, AK.	
11300	Anderson, IN	0.9654
	Madison County, IN.	
11340	Anderson, SC	0.8766
	Anderson County, SC.	
11460	Arbor, MI	1.0086
	Washtenaw County, MI.	
11500	Anniston-Oxford, AL	0.7402
	Calhoun County, AL.	
11540	Appleton, WI	0.9445
	Calumet County, WI.	
	Outagamie County, WI.	
11700	Asheville, NC	0.8511
	Buncombe County, NC.	
	Haywood County, NC.	
	Henderson County, NC.	
	Madison County, NC.	
12020	Athens-Clarke County, GA	0.9244
	Clarke County, GA.	
	Madison County, GA.	
	Oconee County, GA.	
	Oglethorpe County, GA.	
12060	Atlanta-Sandy Springs-Marietta, GA	0.9452
	Barrow County, GA.	
	Bartow County, GA.	
	Butts County, GA.	
	Carroll County, GA.	
	Cherokee County, GA.	
	Clayton County, GA.	
	Cobb County, GA.	
	Coweta County, GA.	
	Dawson County, GA.	
	DeKalb County, GA.	
	Douglas County, GA.	
	Fayette County, GA.	
	Forsyth County, GA.	
	Fulton County, GA.	
	Gwinnett County, GA.	
	Haralson County, GA.	
	Heard County, GA.	
	Henry County, GA.	
	Jasper County, GA.	
	Lamar County, GA.	
	Meriwether County, GA.	
	Newton County, GA.	
	Paulding County, GA.	
	Pickens County, GA.	
	Pike County, GA.	
	Rockdale County, GA.	
	Spalding County, GA.	
	Walton County, GA.	
12100	Atlantic City-Hammonton, NJ	1.2258

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
12220	Atlantic County, NJ.	
12220	Auburn-Opelika, AL	0.7771
12260	Lee County, AL.	
12260	Augusta-Richmond County, GA-SC	0.9150
	Burke County, GA.	
	Columbia County, GA.	
	McDuffie County, GA.	
	Richmond County, GA.	
	Aiken County, SC.	
	Edgefield County, SC.	
12420	Austin-Round Rock-San Marcos, TX	0.9576
	Bastrop County, TX.	
	Caldwell County, TX.	
	Hays County, TX.	
	Travis County, TX.	
	Williamson County, TX.	
12540	Bakersfield-Delano, CA	1.1579
12580	Kern County, CA.	
12580	Baltimore-Towson, MD	0.9873
	Anne Arundel County, MD.	
	Baltimore County, MD.	
	Carroll County, MD.	
	Harford County, MD.	
	Howard County, MD.	
	Queen Anne's County, MD.	
	Baltimore City, MD.	
12620	Bangor, ME	0.9710
	Penobscot County, ME.	
12700	Barnstable Town, MA	1.3007
	Barnstable County, MA.	
12940	Baton Rouge, LA	0.8078
	Ascension Parish, LA.	
	East Baton Rouge Parish, LA.	
	East Feliciana Parish, LA.	
	Iberville Parish, LA.	
	Livingston Parish, LA.	
	Pointe Coupee Parish, LA.	
	St. Helena Parish, LA.	
	West Baton Rouge Parish, LA.	
	West Feliciana Parish, LA.	
12980	Battle Creek, MI	0.9915
	Calhoun County, MI.	
13020	Bay City, MI	0.9486
	Bay County, MI.	
13140	Beaumont-Port Arthur, TX	0.8598
	Hardin County, TX.	
	Jefferson County, TX.	
	Orange County, TX.	
13380	Bellingham, WA	1.1890
	Whatcom County, WA.	
13460	Bend, OR	1.1807
	Deschutes County, OR.	
13644	Bethesda-Rockville-Frederick, MD	1.0319
	Frederick County, MD.	
	Montgomery County, MD.	
13740	Billings, MT	0.8691
	Carbon County, MT.	
	Yellowstone County, MT.	
13780	Binghamton, NY	0.8602
	Broome County, NY.	
	Tioga County, NY.	
13820	Birmingham-Hoover, AL	0.8367
	Bibb County, AL.	
	Blount County, AL.	
	Chilton County, AL.	
	Jefferson County, AL.	
	St. Clair County, AL.	
	Shelby County, AL.	
	Walker County, AL.	
13900	Bismarck, ND	0.7282
	Burleigh County, ND.	

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
13980	Morton County, ND. Blacksburg-Christiansburg-Radford, VA Giles County, VA. Montgomery County, VA. Pulaski County, VA. Radford City, VA.	0.8319
14020	Bloomington, IN Greene County, IN. Monroe County, IN. Owen County, IN.	0.9304
14060	Bloomington-Normal, IL McLean County, IL.	0.9310
14260	Boise City-Nampa, ID Ada County, ID. Boise County, ID. Canyon County, ID. Gem County, ID. Owyhee County, ID.	0.9259
14484	Boston-Quincy, MA Norfolk County, MA. Plymouth County, MA. Suffolk County, MA.	1.2453
14500	Boulder, CO Boulder County, CO.	0.9850
14540	Bowling Green, KY Edmonson County, KY. Warren County, KY.	0.8573
14740	Bremerton-Silverdale, WA Kitsap County, WA.	1.0268
14860	Bridgeport-Stamford-Norwalk, CT Fairfield County, CT.	1.3252
15180	Brownsville-Harlingen, TX Cameron County, TX.	0.8179
15260	Brunswick, GA Brantley County, GA. Glynn County, GA. McIntosh County, GA.	0.8457
15380	Buffalo-Niagara Falls, NY Erie County, NY. Niagara County, NY.	1.0045
15500	Burlington, NC Alamance County, NC.	0.8529
15540	Burlington-South Burlington, VT Chittenden County, VT. Franklin County, VT. Grand Isle County, VT.	1.0130
15764	Cambridge-Newton-Framingham, MA Middlesex County, MA.	1.1146
15804	Camden, NJ Burlington County, NJ. Camden County, NJ. Gloucester County, NJ.	1.0254
15940	Canton-Massillon, OH Carroll County, OH. Stark County, OH.	0.8730
15980	Cape Coral-Fort Myers, FL Lee County, FL.	0.8683
16020	Cape Girardeau-Jackson, MO-IL Alexander County, IL. Bollinger County, MO. Cape Girardeau County, MO.	0.9174
16180	Carson City, NV Carson City, NV.	1.0721
16220	Casper, WY Natrona County, WY.	1.0111
16300	Cedar Rapids, IA Benton County, IA. Jones County, IA. Linn County, IA.	0.8964
16580	Champaign-Urbana, IL Champaign County, IL.	0.9416

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
16620	Ford County, IL. Piatt County, IL. Charleston, WV	0.8119
	Boone County, WV. Clay County, WV. Kanawha County, WV. Lincoln County, WV. Putnam County, WV.	
16700	Charleston-North Charleston-Summerville, SC	0.8972
	Berkeley County, SC. Charleston County, SC. Dorchester County, SC.	
16740	Charlotte-Gastonia-Rock Hill, NC-SC	0.9447
	Anson County, NC. Cabarrus County, NC. Gaston County, NC. Mecklenburg County, NC. Union County, NC. York County, SC.	
16820	Charlottesville, VA	0.9209
	Albemarle County, VA. Fluvanna County, VA. Greene County, VA. Nelson County, VA. Charlottesville City, VA.	
16860	Chattanooga, TN-GA	0.8783
	Catoosa County, GA. Dade County, GA. Walker County, GA. Hamilton County, TN. Marion County, TN. Sequatchie County, TN.	
16940	Cheyenne, WY	0.9494
16974	Laramie County, WY. Chicago-Naperville-Joliet, IL	1.0418
	Cook County, IL. DeKalb County, IL. DuPage County, IL. Grundy County, IL. Kane County, IL. Kendall County, IL. McHenry County, IL. Will County, IL.	
17020	Chico, CA	1.1616
17140	Butte County, CA. Cincinnati-Middletown, OH-KY-IN	0.9470
	Dearborn County, IN. Franklin County, IN. Ohio County, IN. Boone County, KY. Bracken County, KY. Campbell County, KY. Gallatin County, KY. Grant County, KY. Kenton County, KY. Pendleton County, KY. Brown County, OH. Butler County, OH. Clermont County, OH. Hamilton County, OH. Warren County, OH.	
17300	Clarksville, TN-KY	0.7802
	Christian County, KY. Trigg County, KY. Montgomery County, TN. Stewart County, TN.	
17420	Cleveland, TN	0.7496
	Bradley County, TN. Polk County, TN.	
17460	Cleveland-Elyria-Mentor, OH	0.9303
	Cuyahoga County, OH.	

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
17660	Geauga County, OH. Lake County, OH. Lorain County, OH. Medina County, OH. Coeur d'Alene, ID	0.9064
17780	Kootenai County, ID. College Station-Bryan, TX	0.9497
17820	Brazos County, TX. Burleson County, TX. Robertson County, TX. Colorado Springs, CO	0.9282
17860	El Paso County, CO. Teller County, CO. Columbia, MO	0.8196
17900	Boone County, MO. Howard County, MO. Columbia, SC	0.8601
17980	Calhoun County, SC. Fairfield County, SC. Kershaw County, SC. Lexington County, SC. Richland County, SC. Saluda County, SC. Columbus, GA-AL	0.8170
18020	Russell County, AL. Chattahoochee County, GA. Harris County, GA. Marion County, GA. Muscogee County, GA. Columbus, IN	0.9818
18140	Bartholomew County, IN. Columbus, OH	0.9803
18580	Delaware County, OH. Fairfield County, OH. Franklin County, OH. Licking County, OH. Madison County, OH. Morrow County, OH. Pickaway County, OH. Union County, OH. Corpus Christi, TX	0.8433
18700	Aransas County, TX. Nueces County, TX. San Patricio County, TX. Corvallis, OR	1.0596
18880	Benton County, OR. Crestview-Fort Walton Beach-Destin, FL	0.8911
19060	Okaloosa County, FL. Cumberland, MD-WV	0.8054
19124	Allegany County, MD. Mineral County, WV. Dallas-Plano-Irving, TX	0.9831
19140	Collin County, TX. Dallas County, TX. Delta County, TX. Denton County, TX. Ellis County, TX. Hunt County, TX. Kaufman County, TX. Rockwall County, TX. Dalton, GA	0.8625
19180	Murray County, GA. Whitfield County, GA. Danville, IL	0.9460
19260	Vermilion County, IL. Danville, VA	0.7888
19340	Pittsylvania County, VA. Danville City, VA. Davenport-Moline-Rock Island, IA-IL	0.9306
	Henry County, IL. Mercer County, IL.	

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
19380	Rock Island County, IL. Scott County, IA. Dayton, OH	0.9034
19460	Greene County, OH. Miami County, OH. Montgomery County, OH. Preble County, OH. Decatur, AL	0.7165
19500	Lawrence County, AL. Morgan County, AL. Decatur, IL	0.8151
19660	Macon County, IL. Deltona-Daytona Beach-Ormond Beach, FL	0.8560
19740	Volusia County, FL. Denver-Aurora-Broomfield, CO	1.0395
19780	Adams County, CO. Arapahoe County, CO. Broomfield County, CO. Clear Creek County, CO. Denver County, CO. Douglas County, CO. Elbert County, CO. Gilpin County, CO. Jefferson County, CO. Park County, CO. Des Moines-West Des Moines, IA	0.9393
19804	Dallas County, IA. Guthrie County, IA. Madison County, IA. Polk County, IA. Warren County, IA. Detroit-Livonia-Dearborn, MI	0.9237
20020	Wayne County, MI. Dothan, AL	0.7108
20100	Geneva County, AL. Henry County, AL. Houston County, AL. Dover, DE	0.9939
20220	Kent County, DE. Dubuque, IA	0.8790
20260	Dubuque County, IA. Duluth, MN-WI	1.0123
20500	Carlton County, MN. St. Louis County, MN. Douglas County, WI. Durham-Chapel Hill, NC	0.9669
20740	Chatham County, NC. Durham County, NC. Orange County, NC. Person County, NC. Eau Claire, WI	1.0103
20764	Chippewa County, WI. Eau Claire County, WI. Edison-New Brunswick, NJ	1.0985
20940	Middlesex County, NJ. Monmouth County, NJ. Ocean County, NJ. Somerset County, NJ. El Centro, CA	0.8848
21060	Imperial County, CA. Elizabethtown, KY	0.7894
21140	Hardin County, KY. Larue County, KY. Elkhart-Goshen, IN	0.9337
21300	Elkhart County, IN. Elmira, NY	0.8725
21340	Chemung County, NY. El Paso, TX	0.8404
21500	El Paso County, TX. Erie, PA	0.7940
	Erie County, PA.	

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
21660	Eugene-Springfield, OR	1.1723
	Lane County, OR.	
21780	Evansville, IN-KY	0.8381
	Gibson County, IN.	
	Posey County, IN.	
	Vanderburgh County, IN.	
	Warrick County, IN.	
	Henderson County, KY.	
	Webster County, KY.	
21820	Fairbanks, AK	1.0997
	Fairbanks North Star Borough, AK.	
21940	Fajardo, PR	0.3728
	Ceiba Municipio, PR.	
	Fajardo Municipio, PR.	
	Luquillo Municipio, PR.	
22020	Fargo, ND-MN	0.7802
	Cass County, ND.	
	Clay County, MN.	
22140	Farmington, NM	0.9735
	San Juan County, NM.	
22180	Fayetteville, NC	0.8601
	Cumberland County, NC.	
	Hoke County, NC.	
22220	Fayetteville-Springdale-Rogers, AR-MO	0.8955
	Benton County, AR.	
	Madison County, AR.	
	Washington County, AR.	
	McDonald County, MO.	
22380	Flagstaff, AZ	1.2786
	Coconino County, AZ.	
22420	Flint, MI	1.1238
	Genesee County, MI.	
22500	Florence, SC	0.7999
	Darlington County, SC.	
	Florence County, SC.	
22520	Florence-Muscle Shoals, AL	0.7684
	Colbert County, AL.	
	Lauderdale County, AL.	
22540	Fond du Lac, WI	0.9477
	Fond du Lac County, WI.	
22660	Fort Collins-Loveland, CO	0.9704
	Larimer County, CO.	
22744	Fort Lauderdale-Pompano Beach-Deerfield, FL	1.0378
	Broward County, FL.	
22900	Fort Smith, AR-OK	0.7561
	Crawford County, AR.	
	Franklin County, AR.	
	Sebastian County, AR.	
	Le Flore County, OK.	
	Sequoyah County, OK.	
23060	Fort Wayne, IN	0.9010
	Allen County, IN.	
	Wells County, IN.	
	Whitley County, IN.	
23104	Fort Worth-Arlington, TX	0.9535
	Johnson County, TX.	
	Parker County, TX.	
	Tarrant County, TX.	
	Wise County, TX.	
23420	Fresno, CA	1.1768
	Fresno County, CA.	
23460	Gadsden, AL	0.7983
	Etowah County, AL.	
23540	Gainesville, FL	0.9710
	Alachua County, FL.	
	Gilchrist County, FL.	
23580	Gainesville, GA	0.9253
	Hall County, GA.	
23844	Gary, IN	0.9418
	Jasper County, IN.	
	Lake County, IN.	

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
24020	Newton County, IN. Porter County, IN. Glens Falls, NY	0.8367
24140	Warren County, NY. Washington County, NY. Goldsboro, NC	0.8550
24220	Wayne County, NC. Grand Forks, ND-MN	0.7290
24300	Polk County, MN. Grand Forks County, ND. Grand Junction, CO	0.9270
24340	Mesa County, CO. Grand Rapids-Wyoming, MI	0.9091
24500	Barry County, MI. Ionia County, MI. Kent County, MI. Newaygo County, MI. Great Falls, MT	0.9235
24540	Cascade County, MT. Greeley, CO	0.9653
24580	Weld County, CO. Green Bay, WI	0.9587
24660	Brown County, WI. Kewaunee County, WI. Oconto County, WI. Greensboro-High Point, NC	0.8320
24780	Guilford County, NC. Randolph County, NC. Rockingham County, NC. Greenville, NC	0.9343
24860	Greene County, NC. Pitt County, NC. Greenville-Mauldin-Easley, SC	0.9604
25020	Greenville County, SC. Laurens County, SC. Pickens County, SC. Guayama, PR	0.3707
25060	Arroyo Municipio, PR. Guayama Municipio, PR. Patillas Municipio, PR. Gulfport-Biloxi, MS	0.8575
25180	Hancock County, MS. Harrison County, MS. Stone County, MS. Hagerstown-Martinsburg, MD-WV	0.9234
25260	Washington County, MD. Berkeley County, WV. Morgan County, WV. Hanford-Corcoran, CA	1.1124
25420	Kings County, CA. Harrisburg-Carlisle, PA	0.9533
25500	Cumberland County, PA. Dauphin County, PA. Perry County, PA. Harrisonburg, VA	0.9090
25540	Rockingham County, VA. Harrisonburg City, VA. Hartford-West Hartford-East Hartford, CT	1.1050
25620	Hartford County, CT. Middlesex County, CT. Tolland County, CT. Hattiesburg, MS	0.7938
25860	Forrest County, MS. Lamar County, MS. Perry County, MS. Hickory-Lenoir-Morganton, NC	0.8492
25980	Alexander County, NC. Burke County, NC. Caldwell County, NC. Catawba County, NC. Hinesville-Fort Stewart, GA ¹	0.8700

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
26100	Liberty County, GA. Long County, GA. Holland-Grand Haven, MI	0.8016
26180	Ottawa County, MI. Honolulu, HI	1.2321
26300	Honolulu County, HI. Hot Springs, AR	0.8474
26380	Garland County, AR. Houma-Bayou Cane-Thibodaux, LA	0.7525
26420	Lafourche Parish, LA. Terrebonne Parish, LA. Houston-Sugar Land-Baytown, TX	0.9915
26580	Austin County, TX. Brazoria County, TX. Chambers County, TX. Fort Bend County, TX. Galveston County, TX. Harris County, TX. Liberty County, TX. Montgomery County, TX. San Jacinto County, TX. Waller County, TX. Huntington-Ashland, WV-KY-OH	0.8944
26620	Boyd County, KY. Greenup County, KY. Lawrence County, OH. Cabell County, WV. Wayne County, WV. Huntsville, AL	0.8455
26820	Limestone County, AL. Madison County, AL. Idaho Falls, ID	0.9312
26900	Bonneville County, ID. Jefferson County, ID. Indianapolis-Carmel, IN	1.0108
26980	Boone County, IN. Brown County, IN. Hamilton County, IN. Hancock County, IN. Hendricks County, IN. Johnson County, IN. Marion County, IN. Morgan County, IN. Putnam County, IN. Shelby County, IN. Iowa City, IA	0.9854
27060	Johnson County, IA. Washington County, IA. Ithaca, NY	0.9326
27100	Tompkins County, NY. Jackson, MI	0.8944
27140	Jackson County, MI. Jackson, MS	0.8162
27180	Copiah County, MS. Hinds County, MS. Madison County, MS. Rankin County, MS. Simpson County, MS. Jackson, TN	0.7729
27260	Chester County, TN. Madison County, TN. Jacksonville, FL	0.8956
27340	Baker County, FL. Clay County, FL. Duval County, FL. Nassau County, FL. St. Johns County, FL. Jacksonville, NC	0.7861
27500	Onslow County, NC. Janesville, WI	0.9071
	Rock County, WI.	

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
27620	Jefferson City, MO Callaway County, MO. Cole County, MO. Moniteau County, MO. Osage County, MO.	0.8465
27740	Johnson City, TN Carter County, TN. Unicoi County, TN. Washington County, TN.	0.7226
27780	Johnstown, PA Cambria County, PA.	0.8450
27860	Jonesboro, AR Craighead County, AR. Poinsett County, AR.	0.7983
27900	Joplin, MO Jasper County, MO. Newton County, MO.	0.7983
28020	Kalamazoo-Portage, MI Kalamazoo County, MI. Van Buren County, MI.	0.9959
28100	Kankakee-Bradley, IL Kankakee County, IL.	0.9657
28140	Kansas City, MO-KS Franklin County, KS. Johnson County, KS. Leavenworth County, KS. Linn County, KS. Miami County, KS. Wyandotte County, KS. Bates County, MO. Caldwell County, MO. Cass County, MO. Clay County, MO. Clinton County, MO. Jackson County, MO. Lafayette County, MO. Platte County, MO. Ray County, MO.	0.9447
28420	Kennewick-Pasco-Richland, WA Benton County, WA. Franklin County, WA.	0.9459
28660	Killeen-Temple-Fort Hood, TX Bell County, TX. Coryell County, TX. Lampasas County, TX.	0.8925
28700	Kingsport-Bristol-Bristol, TN-VA Hawkins County, TN. Sullivan County, TN. Bristol City, VA. Scott County, VA. Washington County, VA.	0.7192
28740	Kingston, NY Ulster County, NY.	0.9066
28940	Knoxville, TN Anderson County, TN. Blount County, TN. Knox County, TN. Loudon County, TN. Union County, TN.	0.7432
29020	Kokomo, IN Howard County, IN. Tipton County, IN.	0.9061
29100	La Crosse, WI-MN Houston County, MN. La Crosse County, WI.	1.0205
29140	Lafayette, IN Benton County, IN. Carroll County, IN. Tippecanoe County, IN.	0.9954
29180	Lafayette, LA Lafayette Parish, LA.	0.8231

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
29340	St. Martin Parish, LA. Lake Charles, LA	0.7765
29404	Calcasieu Parish, LA. Cameron Parish, LA. Lake County-Kenosha County, IL-WI	1.0658
29420	Lake County, IL. Kenosha County, WI. Lake Havasu City-Kingman, AZ	0.9912
29460	Mohave County, AZ. Lakeland-Winter Haven, FL	0.8283
29540	Polk County, FL. Lancaster, PA	0.9695
29620	Lancaster County, PA. Lansing-East Lansing, MI	1.0618
29700	Clinton County, MI. Eaton County, MI. Ingham County, MI. Laredo, TX	0.7586
29740	Webb County, TX. Las Cruces, NM	0.9265
29820	Dona Ana County, NM. Las Vegas-Paradise, NV	1.1627
29940	Clark County, NV. Lawrence, KS	0.8664
30020	Douglas County, KS. Lawton, OK	0.7893
30140	Comanche County, OK. Lebanon, PA	0.8157
30300	Lebanon County, PA. Lewiston, ID-WA	0.9215
30340	Nez Perce County, ID. Asotin County, WA. Lewiston-Auburn, ME	0.9048
30460	Androscoggin County, ME. Lexington-Fayette, KY	0.8902
30620	Bourbon County, KY. Clark County, KY. Fayette County, KY. Jessamine County, KY. Scott County, KY. Woodford County, KY.	0.9158
30700	Lima, OH	0.9465
30780	Allen County, OH. Lincoln, NE	0.8632
30860	Lancaster County, NE. Seward County, NE. Little Rock-North Little Rock-Conway, AR	0.8754
30980	Faulkner County, AR. Grant County, AR. Lonoke County, AR. Perry County, AR. Pulaski County, AR. Saline County, AR.	0.8933
31020	Logan, UT-ID	1.0460
31084	Franklin County, ID. Cache County, UT. Longview, TX	1.2417
31140	Gregg County, TX. Rusk County, TX. Upshur County, TX. Longview, WA	0.8852
	Cowlitz County, WA. Los Angeles-Long Beach-Glendale, CA	
	Los Angeles County, CA. Louisville-Jefferson County, KY-IN	
	Clark County, IN. Floyd County, IN. Harrison County, IN. Washington County, IN. Bullitt County, KY. Henry County, KY.	

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
	Meade County, KY. Nelson County, KY. Oldham County, KY. Shelby County, KY. Spencer County, KY. Trimble County, KY.	
31180	Lubbock, TX	0.8956
	Crosby County, TX. Lubbock County, TX.	
31340	Lynchburg, VA	0.8771
	Amherst County, VA. Appomattox County, VA. Bedford County, VA. Campbell County, VA. Bedford City, VA. Lynchburg City, VA.	
31420	Macon, GA	0.9014
	Bibb County, GA. Crawford County, GA. Jones County, GA. Monroe County, GA. Twiggs County, GA.	
31460	Madera-Chowchilla, CA	0.8317
	Madera County, CA.	
31540	Madison, WI	1.1414
	Columbia County, WI. Dane County, WI. Iowa County, WI.	
31700	Manchester-Nashua, NH	1.0057
	Hillsborough County, NH.	
31740	Manhattan, KS	0.7843
	Geary County, KS. Pottawatomie County, KS. Riley County, KS.	
31860	Mankato-North Mankato, MN	0.9277
	Blue Earth County, MN. Nicollet County, MN.	
31900	Mansfield, OH	0.8509
	Richland County, OH.	
32420	Mayagüez, PR	0.3762
	Hormigueros Municipio, PR. Mayagüez Municipio, PR.	
32580	McAllen-Edinburg-Mission, TX	0.8393
	Hidalgo County, TX.	
32780	Medford, OR	1.0690
	Jackson County, OR.	
32820	Memphis, TN-MS-AR	0.9038
	Crittenden County, AR. DeSoto County, MS. Marshall County, MS. Tate County, MS. Tunica County, MS. Fayette County, TN. Shelby County, TN. Tipton County, TN.	
32900	Merced, CA	1.2734
	Merced County, CA.	
33124	Miami-Miami Beach-Kendall, FL	0.9870
	Miami-Dade County, FL.	
33140	Michigan City-La Porte, IN	0.9216
	LaPorte County, IN.	
33260	Midland, TX	1.0049
	Midland County, TX.	
33340	Milwaukee-Waukesha-West Allis, WI	0.9856
	Milwaukee County, WI. Ozaukee County, WI. Washington County, WI. Waukesha County, WI.	
33460	Minneapolis-St. Paul-Bloomington, MN-WI	1.1213
	Anoka County, MN. Carver County, MN.	

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
	Chisago County, MN. Dakota County, MN. Hennepin County, MN. Isanti County, MN. Ramsey County, MN. Scott County, MN. Sherburne County, MN. Washington County, MN. Wright County, MN. Pierce County, WI. St. Croix County, WI.	
33540	Missoula, MT	0.9142
	Missoula County, MT.	
33660	Mobile, AL	0.7507
	Mobile County, AL.	
33700	Modesto, CA	1.3629
	Stanislaus County, CA.	
33740	Monroe, LA	0.7530
	Ouachita Parish, LA. Union Parish, LA.	
33780	Monroe, MI	0.8718
	Monroe County, MI.	
33860	Montgomery, AL	0.7475
	Autauga County, AL. Elmore County, AL. Lowndes County, AL. Montgomery County, AL.	
34060	Morgantown, WV	0.8339
	Monongalia County, WV. Preston County, WV.	
34100	Morristown, TN	0.6861
	Grainger County, TN. Hamblen County, TN. Jefferson County, TN.	
34580	Mount Vernon-Anacortes, WA	1.0652
	Skagit County, WA.	
34620	Muncie, IN	0.8743
	Delaware County, IN.	
34740	Muskegon-Norton Shores, MI	1.1076
	Muskegon County, MI.	
34820	Myrtle Beach-North Myrtle Beach-Conway, SC	0.8700
	Horry County, SC.	
34900	Napa, CA	1.5375
	Napa County, CA.	
34940	Naples-Marco Island, FL	0.9108
	Collier County, FL.	
34980	Nashville-Davidson—Murfreesboro-Franklin, TN	0.9141
	Cannon County, TN. Cheatham County, TN. Davidson County, TN. Dickson County, TN. Hickman County, TN. Macon County, TN. Robertson County, TN. Rutherford County, TN. Smith County, TN. Sumner County, TN. Trousdale County, TN. Williamson County, TN. Wilson County, TN.	
35004	Nassau-Suffolk, NY	1.2755
	Nassau County, NY. Suffolk County, NY.	
35084	Newark-Union, NJ-PA	1.1268
	Essex County, NJ. Hunterdon County, NJ. Morris County, NJ. Sussex County, NJ. Union County, NJ. Pike County, PA.	
35300	New Haven-Milford, CT	1.1883

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
35380	New Haven County, CT. New Orleans-Metairie-Kenner, LA Jefferson Parish, LA. Orleans Parish, LA. Plaquemines Parish, LA. St. Bernard Parish, LA. St. Charles Parish, LA. St. John the Baptist Parish, LA. St. Tammany Parish, LA.	0.8752
35644	New York-White Plains-Wayne, NY-NJ Bergen County, NJ. Hudson County, NJ. Passaic County, NJ. Bronx County, NY. Kings County, NY. New York County, NY. Putnam County, NY. Queens County, NY. Richmond County, NY. Rockland County, NY. Westchester County, NY.	1.3089
35660	Niles-Benton Harbor, MI Berrien County, MI.	0.8444
35840	North Port-Bradenton-Sarasota-Venice, FL Manatee County, FL. Sarasota County, FL.	0.9428
35980	Norwich-New London, CT New London County, CT.	1.1821
36084	Oakland-Fremont-Hayward, CA Alameda County, CA. Contra Costa County, CA.	1.7048
36100	Ocala, FL Marion County, FL.	0.8425
36140	Ocean City, NJ Cape May County, NJ.	1.0584
36220	Odessa, TX Ector County, TX.	0.9661
36260	Ogden-Clearfield, UT Davis County, UT. Morgan County, UT. Weber County, UT.	0.9170
36420	Oklahoma City, OK Canadian County, OK. Cleveland County, OK. Grady County, OK. Lincoln County, OK. Logan County, OK. McClain County, OK. Oklahoma County, OK.	0.8879
36500	Olympia, WA Thurston County, WA.	1.1601
36540	Omaha-Council Bluffs, NE-IA Harrison County, IA. Mills County, IA. Pottawattamie County, IA. Cass County, NE. Douglas County, NE. Sarpy County, NE. Saunders County, NE. Washington County, NE.	0.9756
36740	Orlando-Kissimmee-Sanford, FL Lake County, FL. Orange County, FL. Osceola County, FL. Seminole County, FL.	0.9063
36780	Oshkosh-Neenah, WI Winnebago County, WI.	0.9398
36980	Owensboro, KY Daviess County, KY. Hancock County, KY. McLean County, KY.	0.7790

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
37100	Oxnard-Thousand Oaks-Ventura, CA	1.3113
	Ventura County, CA.	
37340	Palm Bay-Melbourne-Titusville, FL	0.8790
	Brevard County, FL.	
37380	Palm Coast, FL	0.8174
	Flagler County, FL.	
37460	Panama City-Lynn Haven-Panama City Beach, FL	0.7876
	Bay County, FL.	
37620	Parkersburg-Marietta-Vienna, WV-OH	0.7569
	Washington County, OH.	
	Pleasants County, WV.	
	Wirt County, WV.	
	Wood County, WV.	
37700	Pascagoula, MS	0.7542
	George County, MS.	
	Jackson County, MS.	
37764	Peabody, MA	1.0553
	Essex County, MA.	
37860	Pensacola-Ferry Pass-Brent, FL	0.7767
	Escambia County, FL.	
	Santa Rosa County, FL.	
37900	Peoria, IL	0.8434
	Marshall County, IL.	
	Peoria County, IL.	
	Stark County, IL.	
	Tazewell County, IL.	
	Woodford County, IL.	
37964	Philadelphia, PA	1.0849
	Bucks County, PA.	
	Chester County, PA.	
	Delaware County, PA.	
	Montgomery County, PA.	
	Philadelphia County, PA.	
38060	Phoenix-Mesa-Scottsdale, AZ	1.0465
	Maricopa County, AZ.	
	Pinal County, AZ.	
38220	Pine Bluff, AR	0.8069
	Cleveland County, AR.	
	Jefferson County, AR.	
	Lincoln County, AR.	
38300	Pittsburgh, PA	0.8669
	Allegheny County, PA.	
	Armstrong County, PA.	
	Beaver County, PA.	
	Butler County, PA.	
	Fayette County, PA.	
	Washington County, PA.	
	Westmoreland County, PA.	
38340	Pittsfield, MA	1.0920
	Berkshire County, MA.	
38540	Pocatello, ID	0.9754
	Bannock County, ID.	
	Power County, ID.	
38660	Ponce, PR	0.4594
	Juana Díaz Municipio, PR.	
	Ponce Municipio, PR.	
	Villalba Municipio, PR.	
38860	Portland-South Portland-Biddeford, ME	0.9981
	Cumberland County, ME.	
	Sagadahoc County, ME.	
	York County, ME.	
38900	Portland-Vancouver-Hillsboro, OR-WA	1.1766
	Clackamas County, OR.	
	Columbia County, OR.	
	Multnomah County, OR.	
	Washington County, OR.	
	Yamhill County, OR.	
	Clark County, WA.	
	Skamania County, WA.	
38940	Port St. Lucie, FL	0.9352
	Martin County, FL.	

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
39100	St. Lucie County, FL. Poughkeepsie-Newburgh-Middletown, NY	1.1544
	Dutchess County, NY. Orange County, NY.	
39140	Prescott, AZ	1.0161
	Yavapai County, AZ.	
39300	Providence-New Bedford-Fall River, RI-MA	1.0539
	Bristol County, MA. Bristol County, RI. Kent County, RI. Newport County, RI. Providence County, RI. Washington County, RI.	
39340	Provo-Orem, UT	0.9461
	Juab County, UT. Utah County, UT.	
39380	Pueblo, CO	0.8215
	Pueblo County, CO.	
39460	Punta Gorda, FL	0.8734
	Charlotte County, FL.	
39540	Racine, WI	0.8903
	Racine County, WI.	
39580	Raleigh-Cary, NC	0.9304
	Franklin County, NC. Johnston County, NC. Wake County, NC.	
39660	Rapid City, SD	0.9568
	Meade County, SD. Pennington County, SD.	
39740	Reading, PA	0.9220
	Berks County, PA.	
39820	Redding, CA	1.4990
	Shasta County, CA.	
39900	Reno-Sparks, NV	1.0326
	Storey County, NV. Washoe County, NV.	
40060	Richmond, VA	0.9723
	Amelia County, VA. Caroline County, VA. Charles City County, VA. Chesterfield County, VA. Cumberland County, VA. Dinwiddie County, VA. Goochland County, VA. Hanover County, VA. Henrico County, VA. King and Queen County, VA. King William County, VA. Louisa County, VA. New Kent County, VA. Powhatan County, VA. Prince George County, VA. Sussex County, VA. Colonial Heights City, VA. Hopewell City, VA. Petersburg City, VA. Richmond City, VA.	
40140	Riverside-San Bernardino-Ontario, CA	1.1497
	Riverside County, CA. San Bernardino County, CA.	
40220	Roanoke, VA	0.9195
	Botetourt County, VA. Craig County, VA. Franklin County, VA. Roanoke County, VA. Roanoke City, VA. Salem City, VA.	
40340	Rochester, MN	1.1662
	Dodge County, MN. Olmsted County, MN. Wabasha County, MN.	

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
40380	Rochester, NY Livingston County, NY. Monroe County, NY. Ontario County, NY. Orleans County, NY. Wayne County, NY.	0.8749
40420	Rockford, IL Boone County, IL. Winnebago County, IL.	0.9751
40484	Rockingham County-Strafford County, NH Rockingham County, NH. Strafford County, NH.	1.0172
40580	Rocky Mount, NC Edgecombe County, NC. Nash County, NC.	0.8750
40660	Rome, GA Floyd County, GA.	0.8924
40900	Sacramento-Arden-Arcade-Roseville, CA El Dorado County, CA. Placer County, CA. Sacramento County, CA. Yolo County, CA.	1.5498
40980	Saginaw-Saginaw Township North, MI Saginaw County, MI.	0.8849
41060	St. Cloud, MN Benton County, MN. Stearns County, MN.	1.0658
41100	St. George, UT Washington County, UT.	0.9345
41140	St. Joseph, MO-KS Doniphan County, KS. Andrew County, MO. Buchanan County, MO. DeKalb County, MO.	0.9834
41180	St. Louis, MO-IL Bond County, IL. Calhoun County, IL. Clinton County, IL. Jersey County, IL. Macoupin County, IL. Madison County, IL. Monroe County, IL. St. Clair County, IL. Crawford County, MO. Franklin County, MO. Jefferson County, MO. Lincoln County, MO. St. Charles County, MO. St. Louis County, MO. Warren County, MO. Washington County, MO. St. Louis City, MO.	0.9336
41420	Salem, OR Marion County, OR. Polk County, OR.	1.1148
41500	Salinas, CA Monterey County, CA.	1.5820
41540	Salisbury, MD Somerset County, MD. Wicomico County, MD.	0.8948
41620	Salt Lake City, UT Salt Lake County, UT. Summit County, UT. Tooele County, UT.	0.9350
41660	San Angelo, TX Irion County, TX. Tom Green County, TX.	0.8169
41700	San Antonio-New Braunfels, TX Atascosa County, TX. Bandera County, TX. Bexar County, TX.	0.8911

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
	Comal County, TX. Guadalupe County, TX. Kendall County, TX. Medina County, TX. Wilson County, TX.	
41740	San Diego-Carlsbad-San Marcos, CA	1.2213
	San Diego County, CA.	
41780	Sandusky, OH	0.7788
	Erie County, OH.	
41884	San Francisco-San Mateo-Redwood City, CA	1.6743
	Marin County, CA. San Francisco County, CA. San Mateo County, CA.	
41900	San Germán-Cabo Rojo, PR	0.4550
	Cabo Rojo Municipio, PR. Lajas Municipio, PR. Sabana Grande Municipio, PR. San Germán Municipio, PR.	
41940	San Jose-Sunnyvale-Santa Clara, CA	1.7086
	San Benito County, CA. Santa Clara County, CA.	
41980	San Juan-Caguas-Guaynabo, PR	0.4356
	Aguas Buenas Municipio, PR. Aibonito Municipio, PR. Arecibo Municipio, PR. Barceloneta Municipio, PR. Barranquitas Municipio, PR. Bayamón Municipio, PR. Caguas Municipio, PR. Camuy Municipio, PR. Canóvanas Municipio, PR. Carolina Municipio, PR. Cataño Municipio, PR. Cayey Municipio, PR. Ciales Municipio, PR. Cidra Municipio, PR. Comerio Municipio, PR. Corozal Municipio, PR. Dorado Municipio, PR. Florida Municipio, PR. Guaynabo Municipio, PR. Gurabo Municipio, PR. Hatillo Municipio, PR. Humacao Municipio, PR. Juncos Municipio, PR. Las Piedras Municipio, PR. Loíza Municipio, PR. Manatí Municipio, PR. Maunabo Municipio, PR. Morovis Municipio, PR. Naguabo Municipio, PR. Naranjito Municipio, PR. Orocovis Municipio, PR. Quebradillas Municipio, PR. Río Grande Municipio, PR. San Juan Municipio, PR. San Lorenzo Municipio, PR. Toa Alta Municipio, PR. Toa Baja Municipio, PR. Trujillo Alto Municipio, PR. Vega Alta Municipio, PR. Vega Baja Municipio, PR. Yabucoa Municipio, PR.	
42020	San Luis Obispo-Paso Robles, CA	1.3036
	San Luis Obispo County, CA.	
42044	Santa Ana-Anaheim-Irvine, CA	1.2111
	Orange County, CA.	
42060	Santa Barbara-Santa Maria-Goleta, CA	1.2825
	Santa Barbara County, CA.	
42100	Santa Cruz-Watsonville, CA	1.7937
	Santa Cruz County, CA.	

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
42140	Santa Fe, NM	1.0136
	Santa Fe County, NM.	
42220	Santa Rosa-Petaluma, CA	1.6679
	Sonoma County, CA.	
42340	Savannah, GA	0.8757
	Bryan County, GA.	
	Chatham County, GA.	
	Effingham County, GA.	
42540	Scranton-Wilkes-Barre, PA	0.8331
	Lackawanna County, PA.	
	Luzerne County, PA.	
	Wyoming County, PA.	
42644	Seattle-Bellevue-Everett, WA	1.1733
	King County, WA.	
	Snohomish County, WA.	
42680	Sebastian-Vero Beach, FL	0.8760
	Indian River County, FL.	
43100	Sheboygan, WI	0.9203
	Sheboygan County, WI.	
43300	Sherman-Denison, TX	0.8723
	Grayson County, TX.	
43340	Shreveport-Bossier City, LA	0.8262
	Bossier Parish, LA.	
	Caddo Parish, LA.	
	De Soto Parish, LA.	
43580	Sioux City, IA-NE-SD	0.9163
	Woodbury County, IA.	
	Dakota County, NE.	
	Dixon County, NE.	
	Union County, SD.	
43620	Sioux Falls, SD	0.8275
	Lincoln County, SD.	
	McCook County, SD.	
	Minnehaha County, SD.	
	Turner County, SD.	
43780	South Bend-Mishawaka, IN-MI	0.9425
	St. Joseph County, IN.	
	Cass County, MI.	
43900	Spartanburg, SC	0.8782
	Spartanburg County, SC.	
44060	Spokane, WA	1.1174
	Spokane County, WA.	
44100	Springfield, IL	0.9165
	Menard County, IL.	
	Sangamon County, IL.	
44140	Springfield, MA	1.0383
	Franklin County, MA.	
	Hampden County, MA.	
	Hampshire County, MA.	
44180	Springfield, MO	0.8440
	Christian County, MO.	
	Dallas County, MO.	
	Greene County, MO.	
	Polk County, MO.	
	Webster County, MO.	
44220	Springfield, OH	0.8447
	Clark County, OH.	
44300	State College, PA	0.9575
	Centre County, PA.	
44600	Steubenville-Weirton, OH-WV	0.7598
	Jefferson County, OH.	
	Brooke County, WV.	
	Hancock County, WV.	
44700	Stockton, CA	1.3734
	San Joaquin County, CA.	
44940	Sumter, SC	0.7594
	Sumter County, SC.	
45060	Syracuse, NY	0.9897
	Madison County, NY.	
	Onondaga County, NY.	
	Oswego County, NY.	

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
45104	Tacoma, WA	1.1574
	Pierce County, WA	
45220	Tallahassee, FL	0.8391
	Gadsden County, FL	
	Jefferson County, FL	
	Leon County, FL	
	Wakulla County, FL	
45300	Tampa-St. Petersburg-Clearwater, FL	0.9075
	Hernando County, FL	
	Hillsborough County, FL	
	Pasco County, FL	
	Pinellas County, FL	
45460	Terre Haute, IN	0.9706
	Clay County, IN	
	Sullivan County, IN	
	Vermillion County, IN	
	Vigo County, IN	
45500	Texarkana, TX-Texarkana, AR	0.7428
	Miller County, AR	
	Bowie County, TX	
45780	Toledo, OH	0.9013
	Fulton County, OH	
	Lucas County, OH	
	Ottawa County, OH	
	Wood County, OH	
45820	Topeka, KS	0.8974
	Jackson County, KS	
	Jefferson County, KS	
	Osage County, KS	
	Shawnee County, KS	
	Wabaunsee County, KS	
45940	Trenton-Ewing, NJ	1.0648
	Mercer County, NJ	
46060	Tucson, AZ	0.8953
	Pima County, AZ	
46140	Tulsa, OK	0.8145
	Creek County, OK	
	Okmulgee County, OK	
	Osage County, OK	
	Pawnee County, OK	
	Rogers County, OK	
	Tulsa County, OK	
	Wagoner County, OK	
46220	Tuscaloosa, AL	0.8500
	Greene County, AL	
	Hale County, AL	
	Tuscaloosa County, AL	
46340	Tyler, TX	0.8526
	Smith County, TX	
46540	Utica-Rome, NY	0.8769
	Herkimer County, NY	
	Oneida County, NY	
46660	Valdosta, GA	0.7527
	Brooks County, GA	
	Echols County, GA	
	Lanier County, GA	
	Lowndes County, GA	
46700	Vallejo-Fairfield, CA	1.6286
	Solano County, CA	
47020	Victoria, TX	0.8949
	Calhoun County, TX	
	Goliad County, TX	
	Victoria County, TX	
47220	Vineland-Millville-Bridgeton, NJ	1.0759
	Cumberland County, NJ	
47260	Virginia Beach-Norfolk-Newport News, VA-NC	0.9121
	Currituck County, NC	
	Gloucester County, VA	
	Isle of Wight County, VA	
	James City County, VA	
	Mathews County, VA	

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
	Surry County, VA. York County, VA. Chesapeake City, VA. Hampton City, VA. Newport News City, VA. Norfolk City, VA. Poquoson City, VA. Portsmouth City, VA. Suffolk City, VA. Virginia Beach City, VA. Williamsburg City, VA.	
47300	Visalia-Porterville, CA	0.9947
	Tulare County, CA.	
47380	Waco, TX	0.8213
	McLennan County, TX.	
47580	Warner Robins, GA	0.7732
	Houston County, GA.	
47644	Warren-Troy-Farmington Hills, MI	0.9432
	Lapeer County, MI. Livingston County, MI. Macomb County, MI. Oakland County, MI. St. Clair County, MI.	
47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	1.0533
	District of Columbia, DC. Calvert County, MD. Charles County, MD. Prince George's County, MD. Arlington County, VA. Clarke County, VA. Fairfax County, VA. Fauquier County, VA. Loudoun County, VA. Prince William County, VA. Spotsylvania County, VA. Stafford County, VA. Warren County, VA. Alexandria City, VA. Fairfax City, VA. Falls Church City, VA. Fredericksburg City, VA. Manassas City, VA. Manassas Park City, VA. Jefferson County, WV.	
47940	Waterloo-Cedar Falls, IA	0.8331
	Black Hawk County, IA. Bremer County, IA. Grundy County, IA.	
48140	Wausau, WI	0.8802
	Marathon County, WI.	
48300	Wenatchee-East Wenatchee, WA	1.0109
	Chelan County, WA. Douglas County, WA.	
48424	West Palm Beach-Boca Raton-Boynton Beach, FL	0.9597
	Palm Beach County, FL.	
48540	Wheeling, WV-OH	0.6673
	Belmont County, OH. Marshall County, WV. Ohio County, WV.	
48620	Wichita, KS	0.8674
	Butler County, KS. Harvey County, KS. Sedgwick County, KS. Sumner County, KS.	
48660	Wichita Falls, TX	0.9537
	Archer County, TX. Clay County, TX. Wichita County, TX.	
48700	Williamsport, PA	0.8268
	Lycoming County, PA.	
48864	Wilmington, DE-MD-NJ	1.0593

TABLE 1—FY 2015 WAGE INDEX FOR URBAN AREAS BASED ON CBSA LABOR MARKET AREAS—Continued

CBSA Code	Urban area (constituent counties)	Wage index
48900	New Castle County, DE. Cecil County, MD. Salem County, NJ. Wilmington, NC	0.8862
49020	Brunswick County, NC. New Hanover County, NC. Pender County, NC. Winchester, VA-WV	0.9034
49180	Frederick County, VA. Winchester City, VA. Hampshire County, WV. Winston-Salem, NC	0.8560
49340	Davie County, NC. Forsyth County, NC. Stokes County, NC. Yadkin County, NC.	1.1584
49420	Worcester, MA	1.0355
49500	Worcester County, MA. Yakima, WA	0.3782
49620	Yakima County, WA. Yauco, PR	0.9540
49660	Guánica Municipio, PR. Guayanilla Municipio, PR. Peñuelas Municipio, PR. Yauco Municipio, PR.	0.8262
49700	York-Hanover, PA	1.1759
49740	York County, PA. Youngstown-Warren-Boardman, OH-PA	0.9674
	Mahoning County, OH. Trumbull County, OH. Mercer County, PA. Yuba City, CA	
	Sutter County, CA. Yuba County, CA.	
	Yuma, AZ	
	Yuma County, AZ.	

¹ At this time, there are no hospitals located in this urban area on which to base a wage index.

TABLE 2—FY 2015 WAGE INDEX
BASED ON CBSA LABOR MARKET
AREAS FOR RURAL AREAS

State code	Nonurban area	Wage index
1	Alabama	0.7147
2	Alaska	1.3662
3	Arizona	0.9166
4	Arkansas	0.7343
5	California	1.2788
6	Colorado	0.9802
7	Connecticut	1.1311
8	Delaware	1.0092
10	Florida	0.7985
11	Georgia	0.7459
12	Hawaii	1.0739
13	Idaho	0.7605
14	Illinois	0.8434
15	Indiana	0.8513
16	Iowa	0.8434
17	Kansas	0.7929
18	Kentucky	0.7784
19	Louisiana	0.7585
20	Maine	0.8238
21	Maryland	0.8696
22	Massachusetts	1.3614
23	Michigan	0.8270

TABLE 2—FY 2015 WAGE INDEX
BASED ON CBSA LABOR MARKET
AREAS FOR RURAL AREAS—Continued

State code	Nonurban area	Wage index
24	Minnesota	0.9133
25	Mississippi	0.7568
26	Missouri	0.7775
27	Montana	0.9098
28	Nebraska	0.8855
29	Nevada	0.9781
30	New Hampshire ..	1.0339
31	New Jersey ¹	0.8922
32	New Mexico	0.8220
33	New York	0.8100
34	North Carolina	0.6785
35	North Dakota	0.8377
36	Ohio	0.7704
37	Oklahoma	0.9435
38	Oregon	0.8430
39	Pennsylvania	0.4047
40	Puerto Rico ¹	0.8329
41	Rhode Island ¹	0.8164
42	South Carolina	
43	South Dakota	

TABLE 2—FY 2015 WAGE INDEX
BASED ON CBSA LABOR MARKET
AREAS FOR RURAL AREAS—Continued

State code	Nonurban area	Wage index
44	Tennessee	0.7444
45	Texas	0.7874
46	Utah	0.8732
47	Vermont	0.9740
48	Virgin Islands	0.7060
49	Virginia	0.7758
50	Washington	1.0529
51	West Virginia	0.7407
52	Wisconsin	0.8904
53	Wyoming	0.9243
65	Guam	0.9611

¹ All counties within the State are classified as urban, with the exception of Puerto Rico. Puerto Rico has areas designated as rural; however, no short-term, acute care hospitals are located in the area(s) for FY 2015. The Puerto Rico wage index is the same as FY 2014.

Addendum C

IPF CODE FIRST TABLE

Code	Code first instructions ICD–10–CM (effective October 1, 2014)
F01.50	Code first the underlying physiological condition or sequelae of cerebrovascular disease.
F01.51	Code first the underlying physiological condition or sequelae of cerebrovascular disease.
F02.80	Code first the underlying physiological condition, such as: A52.17, A81.0–A81.9, E75.00–E75.09, E75.10–E75.19, E75.4, E83.00–E83.09, G10, G30.0–G30.9, G31.01, G31.09, G31.83, G35, G40.001–G40.319, G40.401–G40.919, G40.A01–G40.B19, M30.8. This list is a translation of the ICD–9 codes rather than a list of the conditions in the ICD–10 codebook code first note for category F02.
F02.81	Code first the underlying physiological condition, such as: A52.17, A81.0–A81.9, E75.00–E75.09, E75.10–E75.19, E75.4, E83.00–E83.09, G10, G30.0–G30.9, G31.01, G31.09, G31.83, G35, G40.001–G40.319, G40.401–G40.919, G40.A01–G40.B19, M30.8.
F04	Code first the underlying physiological condition.
F05	Code first the underlying physiological condition, such as: A52.17, A81.0–A81.9, E75.00–E75.09, E75.10–E75.19, E75.4, E83.00–E83.09, G10, G30.0–G30.9, G31.01, G31.09, G31.83, G35, G40.001–G40.319, G40.401–G40.919, G40.A01–G40.B19, M30.8.
F06.0	Code first the underlying physiological condition.
F06.1	Code first the underlying physiological condition.
F06.2	Code first the underlying physiological condition.
F06.30	Code first the underlying physiological condition.
F06.31	Code first the underlying physiological condition.
F06.32	Code first the underlying physiological condition.
F06.33	Code first the underlying physiological condition.
F06.34	Code first the underlying physiological condition.
F06.4	Code first the underlying physiological condition.
F06.8	Code first the underlying physiological condition.
F45.42	Code also associated acute or chronic pain.

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Part IV

Department of Transportation

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 171, 172, 173, et al.

Hazardous Materials: Transportation of Lithium Batteries; Final Rule

DEPARTMENT OF TRANSPORTATION**Pipeline and Hazardous Materials
Safety Administration****49 CFR Parts 171, 172, 173, 175****[Docket No. PHMSA–2009–0095 (HM–224F)]****RIN 2137–AE44****Hazardous Materials: Transportation of
Lithium Batteries****AGENCY:** Pipeline and Hazardous
Materials Safety Administration
(PHMSA), DOT.**ACTION:** Final rule.

SUMMARY: PHMSA, in consultation with the Federal Aviation Administration (FAA), is modifying the requirements governing the transportation of lithium cells and batteries. This final rule revises hazard communication and packaging provisions for lithium batteries and harmonizes the Hazardous Materials Regulations (HMR) with applicable provisions of the United Nations (UN) Model Regulations, the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions) and the International Maritime Dangerous Goods (IMDG) Code.

DATES: *Effective Date:* August 6, 2014.

Voluntary Compliance Date:
Voluntary compliance with all amendments is authorized August 6, 2014.

Delayed Compliance Date: Unless otherwise specified, compliance with the amendments adopted in this final rule is February 6, 2015.

The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of August 6, 2014.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:**Contents**

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I. Executive Summary

In this final rule, PHMSA is revising requirements in the HMR applicable to the transport of lithium cells and batteries consistent with the UN Model Regulations, the ICAO Technical Instructions and the IMDG Code. The final rule:

- (1) Replaces equivalent lithium content with Watt-hours for lithium ion cells and batteries;
- (2) adopts separate shipping descriptions for lithium metal batteries and lithium ion batteries;
- (3) revises provisions for the transport of small and medium lithium cells and batteries including cells and batteries packed with, or contained in, equipment;
- (4) revises the requirements for the transport of lithium batteries for disposal or recycling;
- (5) harmonizes the provisions for the transport of low production and prototype lithium cells and batteries with the ICAO Technical Instructions and the IMDG Code; and
- (6) adopts new provisions for the transport of damaged, defective, and recalled lithium batteries.

PHMSA is not adopting proposals to:

- (1) Modify provisions for what constitutes a change to a battery design in the UN Manual of Tests and Criteria;
- (2) require lithium cells and batteries to be marked with an indication that the cell or battery design passed each of the appropriate tests outlined in the UN Manual of Tests and Criteria; or (3) limit the locations on board aircraft where shipments of lithium cells and batteries could be stowed.

The provisions of this final rule are consistent with Section 828 of the “FAA Modernization and Reform Act of 2012” (Pub. L. 112–98, 126 Stat.133 (Feb. 14, 2012)), which prohibits DOT from issuing or enforcing any regulation or other requirement regarding the air transportation of lithium cells or batteries if the requirement is more

stringent than the requirements of the ICAO Technical Instructions.

PHMSA estimates that the costs of this rule would total \$12.1 million over the next 10 years when applying a 3 percent discount rate, and \$10.8 million when applying a 7 percent rate. PHMSA also developed high and low cost estimates to incorporate uncertainty in quantifying costs—at a 7 percent discount rate the low estimate of costs is \$7.4 million and the high estimate is \$15.0 million. These figures acknowledge that the HMR already authorize the use of the ICAO Technical Instructions and the IMDG Code for most lithium battery shipments. Further, shipments of lithium batteries transported to or from the U.S. must conform to either the ICAO Technical Instructions by air or the IMDG code by vessel. Domestic air and vessel transport of lithium batteries is the final remaining segment likely to be impacted by the amendments in this final rule. Commenters representing air carriers indicated that international operators and most U.S. operators conform to the provisions of the ICAO Technical Instructions because of the desire to have a single set of operational practices and training standards. PHMSA anticipates cost savings resulting from harmonization of certain requirements, including those related to proper shipping names and Watt-hour ratings. Separate entries for lithium metal and lithium ion batteries have appeared in the ICAO Technical Instructions and the IMDG code since 2009. PHMSA did not adopt those entries at that time but noted that the then new entries could be used both domestically and internationally, and for transportation by motor vehicle and rail immediately before or after being transported by aircraft. [74 FR 2207]. While the HMR permit the use of these shipping descriptions because these entries do not appear in the Hazardous Materials Table (HMT; § 172.101) use of these descriptions continues to frustrate shipments. Similarly, the ICAO Technical Instructions and the IMDG code use the term “Watt-hours” to measure the size of lithium ion batteries, while the HMR use the term “equivalent lithium content.” While both of these provide an indication of the size of a lithium ion battery, they are not interchangeable units and this difference frustrates shippers attempting to determine the appropriate shipping requirements. PHMSA anticipates some safety benefits resulting from risk reduction through a combination of: Reliable packaging; hazard communication; inspection and

acceptance checks prior to loading cargo aboard aircraft; pilot notification; and employee training, many of which have already been adopted into current practice.

II. Background

PHMSA published a notice of proposed rulemaking (NPRM) in this docket (75 FR 1302, Jan. 11, 2010) to enhance the transport of lithium cells and batteries through elimination of regulatory exceptions, increased battery design testing requirements, air cargo stowage requirements, and clarification of certain other provisions. In that NPRM, PHMSA discussed: (1) National Transportation Safety Board (NTSB) Recommendations resulting from the February 7, 2006, cargo aircraft accident at Philadelphia International Airport suspected to have been caused by lithium batteries; (2) numerous minor incidents of smoke or fire involving lithium cells and batteries in air transportation, which may be “precursors” to a catastrophic accident; and (3) research conducted by FAA William J. Hughes Technical Center (Technical Center), which examined the characteristics of fires involving packages of lithium batteries, the effectiveness of conventional fire suppression systems at mitigating the impacts of these fires, and the ability of packages to contain a fire involving lithium batteries. 75 FR at 1303–07. Specifically, in the NPRM, PHMSA proposed to:

- Adopt or revise various definitions of: “Lithium cell or battery”; “lithium content”; “lithium ion cell or battery”; “lithium metal cell or battery”; “short circuit”; and “Watt-hour.”
- Adopt Watt-hour, in place of “equivalent lithium content”, as the measure of power (or size) of a lithium ion cell or battery.
- Require a shipper, carrier, package owner, or person reporting an incident provide reasonable assistance in an investigation including access to the damaged package or article.
- Replace the single proper shipping name and UN identification number for “lithium batteries” with separate proper shipping names and UN identification numbers for lithium metal batteries and lithium ion batteries and also adopt separate proper shipping names and UN identification numbers for lithium metal and lithium ion batteries packed with, or contained in, equipment.
- Consolidate requirements for shipping lithium cells and batteries, and exceptions into § 173.185, by:
 - Requiring cells and batteries to be tested in accordance with the latest revisions to the UN Manual of Tests and

Criteria, and require manufacturers to retain evidence of successful completion of UN testing. PHMSA also indicated it was considering requiring the presence of a “quality mark” to indicate successful testing.

- Eliminating the exceptions for small cells and batteries in air transportation, except with respect to extremely small cells packed with or contained in equipment.
- Providing certain relaxed requirements for (1) the shipment of low production runs and prototype batteries, and (2) batteries being shipped for recycling or disposal.

- Require lithium cells and batteries, when transported by aircraft, to be stowed in a location accessible by a crew member or a location equipped with an FAA-approved detection and fire suppression system.

PHMSA proposed an effective date for a final rule 75 days after publication in the **Federal Register** and invited comments concerning the additional costs that would result from such a compliance schedule, practical difficulties associated with quickly coming into compliance with the provisions of the January 11, 2010, NPRM, and any other issues that PHMSA should consider in making a decision on the compliance schedule. PHMSA also invited commenters to address the feasibility and practicability of a phased compliance schedule, under which certain provisions of the final rule would become effective on a faster schedule than other provisions, for which immediate compliance would be more difficult.

A total of 125 persons submitted comments on the proposals in the January 11, 2010, NPRM. Commenters included battery and electrical device manufacturers, airlines, airline pilots, retailers, battery recyclers, members of the U.S. House of Representatives, the U.S. Small Business Administration (SBA), the U.S. Chamber of Commerce, and foreign governments. PHMSA also received comments from industry trade associations and other advocates representing the above named groups.

Commenters expressed support for the overall goal of improving the safe transport of lithium batteries by all modes, especially air. The commenters also stressed the need for consistency between the HMR and the ICAO Technical Instructions. Several commenters suggested that even small deviations from the ICAO Technical Instructions in the transport of lithium batteries would cause significant disruptions. These commenters stated that differences between U.S. and international requirements for lithium

batteries detract from safety by creating confusion and excessively complicating the detailed set of regulations that already apply to lithium battery shipments. SBA recommended that PHMSA consider the public comments to the proposed rule, assess the impact of the proposed rule on small businesses, and consider feasible alternatives that would meet the agency’s safety objectives while minimizing the economic impact on small business.

The majority of commenters focused on the proposals for: (1) Eliminating provisions for small lithium batteries currently found in § 172.102, special provision 188; (2) modifying the criteria under which a lithium battery would be considered to be a new type; and (3) prescribing aircraft stowage requirements. To review the NPRM, draft regulatory evaluation, environmental assessment, comments, letters, and other materials considered in this regulatory action go to <http://www.regulations.gov>, docket number PHMSA–2009–0095. To locate a specific commenter by name simply use the search function provided by [regulations.gov](http://www.regulations.gov).

Since publication of the January 11, 2010 NPRM:

- PHMSA hosted a public meeting attended by 100 individuals (outside of PHMSA and FAA) representing a total of 73 companies, organizations and other entities, 16 of whom made presentations. A transcript of this meeting is in the docket (at PHMSA–2009–0095–0189).¹

- The FAA Technical Center continued to study the risks presented by lithium batteries in air transportation and ways to address those risks and published reports on “Fire Protection for the Shipment of Lithium Batteries in Aircraft Cargo Compartments” (November 2010) and, in conjunction with Transport Canada, on a “Freighter Airplane Cargo Fire Risk Model” (September 2011). Copies of these reports are in the docket (at PHMSA–2009–0095–0235 and –0240, respectively).

- PHMSA evaluated transportation incidents involving lithium batteries and one cargo aircraft accident in which an aircraft transporting lithium batteries

¹ In addition, representatives of the Cargo Airline Association met with officials of the FAA on September 8, 2010, to present additional concerns with proposals in the NPRM, and a member of the Airline Pilots Association provided information to PHMSA on aircraft fire suppression systems, the notice to the pilot in command, and current training of airline personnel in a telephone conference on April 20, 2011. Memoranda of these contacts are in the docket (at PHMSA–2009–0095–0220 and –0234, respectively).

was destroyed and both pilots were killed.²

- The ICAO Dangerous Goods Panel adopted revisions into the 2013–2014 ICAO Technical Instructions that narrow exceptions for lithium metal and lithium ion cells and batteries not packed with, or contained in, equipment when transported by aircraft. PHMSA incorporated the 2013–2014 ICAO Technical Instructions by reference into the HMR in docket number PHMSA2012–0027 (HM–215L), 78 FR 988 (January 7, 2013).³

- In February 2012, Congress passed and the president signed the “FAA Modernization and Reform Act of 2012” that specifically prohibits DOT agencies from issuing or enforcing regulations regarding the air transport of lithium cells or batteries, whether transported separately or packed with, or contained in, equipment, if the requirement is more stringent than the requirements of the ICAO Technical Instructions.⁴

- In April 2012 and January 2013, PHMSA stated that it was considering harmonizing requirements in the HMR on the transportation of lithium batteries with changes adopted in the 2013–2014 ICAO Technical Instructions and requested additional comments on (1) the effect of those changes, (2) whether to require compliance with the ICAO Technical Instructions for all shipments by air, both domestic and international, and (3) the impacts if PHMSA failed to adopt specific provisions in the ICAO Technical Instructions into the HMR. 77 FR 21714 (Apr. 11, 2012), 78 FR 1119 (Jan. 7, 2013).

The changes adopted in the ICAO Technical Instructions require additional shipper training, markings, labels, and pilot notification for packages containing more than 8

lithium cells or 2 lithium batteries, which were previously not subject these requirements. Commenters to the April 11, 2012 and the January 7, 2013 notices unanimously supported harmonization of the HMR with the 2013–2014 ICAO Technical Instructions while acknowledging that the changes adopted by the ICAO would result in increased costs in training, package markings and revised procedures. Commenters also noted that, if PHMSA failed to harmonize the HMR with the current ICAO Technical Instructions, shippers and carriers would continue to struggle with the differences between the two sets of regulations. Commenters further stated that PHMSA should not adopt proposals in the NPRM that would be more restrictive than the ICAO Technical Instructions because this would place U.S. shippers and carriers at a disadvantage relative to their international counterparts and be in violation of the FAA Modernization and Reform Act of 2012. Commenters also opposed specifically maintaining an option to use the current HMR, instead of the ICAO Technical Instructions, and noted that permitting shippers and carriers to choose compliance with alternative standards in domestic and international commerce would undermine safety because the ICAO provisions are more stringent than the current HMR.

Several air carriers indicated that because the 2013–2014 ICAO Technical Instructions would become effective January 1, 2013 they would be in compliance with those standards by that date regardless of whether (or when) PHMSA issued a final rule. Other commenters requested a transition period between 6 and 18 months to permit companies to conduct training and adjust their operations to adapt to these changes. Outside of a delayed compliance date, commenters did not suggest any other ways to reduce the compliance burden. The National Association of Manufacturers (NAM) indicated that supply chains will have to adapt to a final rule that adopts the provisions of the 2013–2014 ICAO Technical Instructions, but the costs of implementing these provisions would vary from one manufacturer to another. The Cargo Airline Association (CAA) suggested that the revisions in the 2013–2014 ICAO Technical Instructions might result in a shift in transport from the air mode to other modes (such as ground) but did not attempt to quantify this as shipping decisions would vary from company to company.

Air carriers and international shippers stressed the desire for a single system to eliminate errors and streamline training.

Further, the commenters asserted that any benefits associated with maintaining an option would be minor, accrued by a small number of entities and that these benefits would be more than offset by increased confusion experienced by shippers and air carriers. Additionally, commenters suggested that a failure by PHMSA to mandate the use of the ICAO Technical Instructions would create an environment where the U.S. permits a lesser standard than the rest of the world, placing air carriers and pilots at increased risk and hampering enforcement of the ICAO Technical Instructions.

Based on all the comments received, and our analysis of the recent changes to the ICAO Technical Instructions, we are adopting into the HMR requirements consistent with 2013–2014 ICAO Technical Instructions, the 17th revised edition of the UN Model Regulations, the 5th Revised Edition of the UN Manual of Tests and Criteria Amendment 1, and Amendment 36–12 of the IMDG Code. In the section-by-section review, each of the proposals, with corresponding comments, and subsequent revisions is discussed in more detail. For convenience, a list of commenters is provided below:

3M Company
Airlines for America (A4A), formerly Air Transport Association (ATA)
ACCO Brands (ACCO)
Advanced Medical Technology Association (AdvaMed)
Airforwarders Association (Afa)
The Airline Pilots Association, International (ALPA)
Airtec GmbH & Co. KG (Airtec)
Alaska Airlines
The American Trucking Associations (Trucking)
Association of Hazmat Shippers, Inc. (AHS)
Association of International Automobile Manufacturers, Inc. (AIAM)
Asurion Corporation
AT&T Services Inc.
Batteries Plus LLC
Battery Association of Japan (BAJ)
Bayer HealthCare Diabetes Care
Berlin Heart Inc.
Best Buy Corporation
Biomet Incorporated
Black & Decker
Boat U.S. Foundation
Boston Power
Boston Scientific Corporation
Camera and Imaging Products Association (CIPA)
Cargo Airline Association (CAA)
Casio America (Casio)
Clean Harbors Environmental Services
Coalition of Airline Pilots Associations (CAPA)
Communications and Information Network Association of Japan (CIAJ)
CompuCom Systems, Inc.
Consumer Electronics Association (CEA)

² On September 3, 2010, in Dubai, United Arab Emirates, a 747–400 cargo aircraft crashed while attempting to land at the Dubai airport after a fire was discovered. Both pilots were killed, and the aircraft and its cargo, which included lithium batteries, were destroyed. The UAE preliminary report of the accident is in the docket (at PHMSA–2009–0095–0238).

³ This means that, for purposes of the HMR, a shipment of lithium batteries to, from, or within the United States could be offered and transported in accordance with the current edition of the ICAO Technical Instructions even before PHMSA issued a final rule in this proceeding.

⁴ The legislation allows the continued prohibition on the transport of lithium metal cells and batteries aboard passenger aircraft. It also authorizes the issuance of more stringent regulation based on credible reports that lithium batteries substantially contributed to the initiation or propagation of a fire aboard an aircraft, as long as the regulations address solely the deficiencies referenced in the report(s) and are the least disruptive and least expensive variation from existing requirements while adequately addressing identified deficiencies.

Consumer Electronics Retail Coalition (CERC)
 Control Technology Inc.
 Corporate Radiation Safety and Dangerous Goods Transport (Siemens)
 Council on Safe Transport of Hazardous Articles (COSTHA)
 Covidien
 CTIA—The Wireless Association
 Dangerous Goods Advisory Council (DGAC)
 Dangerous Goods Trainers Association (DGTA)
 Delphi Automotive (Delphi)
 Delta Airlines (Delta)
 Deutsche Post DHL (DHL)
 DGM USA
 Digital Europe
 Embassy of Israel
 Embassy of the Republic of Korea
 Energizer Battery Manufacturing, Inc. (Energizer)
 EnteroMedics, Inc.
 Environmental Technology Council
 European Portable Battery Association (EPBA)
 European Union
 Express Association of America (EAA)
 Fedco Electronics, Inc. (FedCo)
 FedEx Express (FedEx)
 Garmin International, Inc. (Garmin)
 GE Corporation (GE)
 GRC Wireless Recycling (GRC)
 Greatbatch, Inc.
 Hephner TV & Electronics
 Hitachi Maxell, Ltd.
 Horizon Air
 International Air Transport Association (IATA)
 Infinite Power Solutions, Inc.
 Information Technology Industry Council (ITI)
 Infotrac
 International Federation of Airline Pilots Associations (IFALPA)
 The Japan Electrical Manufacturer's Association (JEMA)
 Japan Electronics & Information Technology Industries Association (JEITA)
 Japan Machinery Center for Trade and Investment (JMC)
 Johnson Controls
 Korea International Trade Association (KITA), the Korea Electronics Association (KEA), and the Battery R&D Association of Korea (KORBA)
 Learjet Inc.
 Leroy Bennet
 Lifescan, Inc. and Animas Corporation
 Lithium Battery Industry Coalition
 Medical Device Manufacturers Association (MDMA)
 Medtronic, Inc.
 Mercedes-Benz USA, LLC
 MicroSun Technologies LLC
 Motorola, Inc.
 National Association of Manufacturers (NAM)
 National Fire Protection Association (NFPA)
 National Funeral Directors Association (NFDA)
 The National Industrial Transportation League (NITL)
 National Retail Federation (NRF)
 National Transportation Safety Board (NTSB)
 National Electrical Manufacturers Association (NEMA)

NetApp, Inc.
 Nexergy
 National Institute of Standards and Technology/US Department of Commerce (on behalf of Japan and on behalf of Korea)
 Nokia Inc.
 The North American Automotive Hazmat Action Committee (NAAHAC)
 Northern Air Cargo (NAC)
 Olympus Corporation of the Americas (Olympus)
 Organ Recovery Systems, Inc.
 Palladium Energy
 Panasonic Corporation of America (Panasonic)
 Photo Marketing Association
 Quallion LLC (Quallion)
 RadioShack Corporation
 Recharge
 The Rechargeable Battery Association (PRBA)
 Rechargeable Battery Recycling Corporation (RBRCC)
 Rep. Don Young
 Rep. John Mica
 Rep. Robert E. Latta
 Retail Industry Leaders Association (RILA)
 Rockwell Automation
 Rose Electronics Distributing Company
 Saft
 Small Business Administration Office of Advocacy (SBA)
 Security Industry Association
 Southwest Airlines, Co. (Southwest)
 Sprint Nextel Corporation (Sprint)
 SRICI Testing Center
 St. Jude Medical, Inc.
 SureFire LLC
 Techtronic Industries (TTi)
 The International Air Cargo Association (TIACA)
 TNR Technical, Inc.
 Transportation Intermediaries Association (TIA)
 Transportation Trades Department AFL–CIO (TDD)
 Troy Rank
 Tyco Electronics
 Tyco International
 United Parcel Service (UPS)
 United Technologies Corporation (UTC)
 URS Corporation (URS)
 US Chamber of Commerce

III. Section-by-Section Review

A. Part 171

Section 171.8 Definitions

In the NPRM, PHMSA proposed to remove, add and amend a number of definitions applicable to lithium batteries, as follows:

1. Remove the definition for “equivalent lithium content” and replace that term with “Watt-hour” consistent with the UN Manual of Tests and Criteria. Commenters supported the proposed addition of the term “Watt-hour” in place of “equivalent lithium content” as a method to measure the size of lithium ion cells and batteries.
3. Provide separate definitions for “lithium metal cell or battery” and “lithium ion cell or battery” in order to differentiate between the different

lithium battery chemistries, and a definition of “Short circuit” consistent with the 5th revised edition of the UN Manual of Tests and Criteria, Amendment 1 and revise the definitions of “Aggregate lithium content” and “Lithium content” also consistent with the 5th revised edition of the UN Manual of Tests and Criteria, Amendment 1. PHMSA did not receive any negative comments regarding these proposed changes.

In this final rule, we are adding definitions for “Lithium ion cell or battery,” “Lithium metal cell or battery,” “Short circuit” and “Watt-hour” as proposed. We are removing the present definitions of “aggregate lithium content,” “equivalent lithium content,” and “lithium content.” The explanation of the size or energy of a cell or battery is being incorporated into the definition of lithium metal cell or battery and lithium ion cell or battery. The term “Aggregate lithium content” is not used in the HMR.

Section 171.21 Assistance in Investigations

In § 171.21, PHMSA requires a shipper, carrier, package owner, package manufacturer or certifier, repair facility, or person reporting a hazardous materials transportation incident to provide assistance to authorized representatives of the Department of Transportation investigating the incident. In the NPRM, PHMSA proposed to specifically require such persons to provide reasonable access to a damaged package or article involved in a transportation incident. PHMSA proposed these revisions in response to NTSB Recommendation A–07–107 that recommends retaining failed lithium batteries or devices for further analysis. After an incident, often the only evidence provided to PHMSA and the FAA is a written incident report, and in some instances, pictures of the involved package or article. In some cases, analysis of the damaged article may reveal the cause of the incident.

NEMA supported this proposal and suggested that, if this requirement had been in place earlier, PHMSA and the FAA would possess more information regarding the causes of many of the lithium battery incidents cited in the NPRM. UPS and URS request clarification on the phrases “reasonable access” and “if available,” noting that the term “reasonable” is not defined. NAC raised environmental and safety concerns associated with the storage of hazardous materials in the workplace. NTSB stated that PHMSA could significantly improve the NPRM if

retention and analysis of failed batteries and equipment were required.

After reading the comments and reexamining the proposal, we concluded that the regulations as currently written already meet the intent of recommendation A-07-107. Specifically §§ 109.3 and 109.9 permit a designated agent of the U.S. DOT to gather information in support of an investigation and direct a package to be transported to a facility for examination to evaluate whether the package conforms to the appropriate requirements. Based on the particular circumstances involved in an incident investigation PHMSA may decide to examine failed batteries or devices. In the case of lithium batteries, the decision about whether PHMSA will retain and examine the remains of a lithium battery incident depend on the condition of the package or article involved in the incident (e.g., where did the incident occur, did the incident involve other packages, are there sufficient remains to examine, can the cause be determined based on other evidence?) PHMSA uses this information to conduct follow-up investigations as necessary.

Sections 171.12, 171.22, 171.23, 171.24, 171.25 Use of International Standards and Regulations

The HMR, ICAO Technical Instructions, IMDG Code, and the Transport Canada TDG Regulations are based on the UN Recommendations, which are model regulations issued by the UN Committee of Experts on the Transport of Dangerous Goods. The HMR, with certain conditions and limitations, permit both domestic and international shipments of hazardous materials to be offered for transportation and transported under provisions of, the ICAO Technical Instructions, the IMDG Code and the TDG Regulations as appropriate. In most cases where we allow compliance with an alternative

standard such as the ICAO Technical Instructions or the IMDG Code, the level of safety is at least equal to the HMR. However, in a limited number of situations additional conditions or limitations are necessary consistent with the public interest or are required to comply with other federal law. Examples of these condition or limitations include but are not limited to: Approval of Class 1 (explosive) materials; identification of hazardous substances and hazardous wastes; and the prohibition on the transport of lithium metal batteries by passenger aircraft.

In the NPRM, PHMSA proposed more stringent requirements than the ICAO Technical Instructions and the IMDG Code that were effective at the time the NPRM was published. Most commenters strongly recommended that we adopt the standards set forth in the ICAO Technical Instructions and the IMDG code, rather than the more stringent requirements proposed in the NPRM. These commenters contended that the proposed amendments would create confusion, decrease compliance, and negatively impact safety throughout the supply chain. Since the NPRM was published, the ICAO Technical Instructions have been revised several times and provide additional protections not found in the current HMR including a reduction in the number of batteries permitted in a package, employee training and explicit hazard communication. Accordingly, we would be continuing to allow a lower level of safety for the domestic transportation of lithium cells and batteries if we do not harmonize the HMR with the 2013-2014 ICAO Technical Instructions.

DGAC noted the provisions in the proposed § 171.12(a)(6)(i) would effectively impose less stringent requirements for shipments originating in Canada than PHMSA proposed for domestic shipments by rail or highway.

PHMSA intends all lithium batteries offered for transport to, from, or through the United States in accordance with the Canadian TDG regulations to also comply with the appropriate requirements of the HMR.

Based on those comments received, and our analysis of the requirements of the 2013-2014 ICAO Technical Instructions, we are adopting into the HMR requirements consistent with 2013-2014 ICAO Technical Instructions, the 17th revised edition of the UN Model Regulations, the 5th Revised Edition of the UN Manual of Tests and Criteria Amendment 1, and Amendment 36-12 of the IMDG Code. In this final rule, we are amending §§ 171.12, 171.24 and 171.25 to reflect the revised proper shipping names for lithium metal batteries, already found in the ICAO Technical Instructions and the IMDG Code and we will maintain the current prohibition on the transport of lithium metal batteries aboard passenger aircraft.

B. Part 172

Section 172.101 Hazardous Materials Table

At present, the Hazardous Materials Table (HMT) in § 172.101 contains three entries for lithium batteries. (1) Lithium battery (UN3090), (2) Lithium batteries, contained in equipment (UN3091), and (3) Lithium batteries packed with equipment (UN3091). In the NPRM we proposed to adopt separate entries for lithium metal and lithium ion batteries (including lithium metal and lithium ion batteries packed with, or contained in, equipment) to be consistent with the UN Model Regulations, the ICAO Technical Instructions and the IMDG Code. Commenters to the NPRM supported the clarification brought by the separate shipping descriptions. In this final rule, PHMSA is adopting the new HMT entries shown in the chart below:

Lithium ion batteries <i>including lithium ion polymer batteries</i>	UN3480, 9, II
Lithium ion batteries contained in equipment <i>including lithium ion polymer batteries</i>	UN3481, 9, II
Lithium ion batteries packed with equipment <i>including lithium ion polymer batteries</i>	UN3481, 9, II
Lithium metal batteries <i>including lithium alloy batteries</i>	UN3090, 9, II
Lithium metal batteries contained in equipment <i>including lithium alloy batteries</i>	UN3091, 9, II
Lithium metal batteries packed with equipment <i>including lithium alloy batteries</i>	UN3091, 9, II

DGAC and IATA asked PHMSA to clarify the quantity limits for lithium batteries packed with, or contained in, equipment. DGAC recommended that PHMSA clarify that the mass limit applies to the mass of batteries in or with equipment, excluding the weight of the accompanying equipment and packaging. IATA requested that PHMSA

align the quantity limits shown in column 9 of the hazardous materials table with respect to batteries contained in equipment with the ICAO Technical Instructions. The aircraft quantity limits for lithium batteries including lithium batteries packed with, or contained in, equipment in this final rule are aligned with package limits described in the

2013-2014 ICAO Technical Instructions.

Section 172.102 Special Provisions

Section 172.102 contains special provisions applicable to the transportation of specific hazardous materials. In this final rule, PHMSA is

removing and revising several special provisions as follows:

Special Provision 29

Special provision 29 outlines provisions for the transport of low production runs of lithium batteries. As proposed in the NPRM, PHMSA is deleting special provision 29 and combining the transport provisions for low production runs with the transport provisions for prototype lithium batteries into § 173.185(e). See the detailed discussion of the revisions to § 173.185 below.

Special Provision 134

Special provision 134 applies to vehicles powered by wet batteries, sodium batteries, or lithium batteries and equipment powered by wet batteries or sodium batteries that are transported with these batteries installed. In this final rule, PHMSA is revising special provision 134 to reflect the adoption of separate shipping descriptions for lithium ion batteries and lithium metal batteries.

Special Provisions 188, 189

Special provisions 188 and 189 contain transport provisions for “small” and “medium” lithium cells and batteries. These provisions are being revised and moved to § 173.185(c). Consequently, in this final rule, PHMSA is deleting special provisions 188 and 189. See the detailed discussion of the revisions to § 173.185 below.

Special Provision 190

Special provision 190 contains transitional provisions enacted in a previous rulemaking pertaining to lithium batteries published August 9, 2007 (72 FR 44930). The transition period shown in special provision 190 has expired and is no longer effective. In this final rule, PHMSA is deleting special provision 190.

Special Provision 328

Special provision 328 applies to fuel cell systems that also contain lithium batteries. In this final rule, PHMSA is revising this special provision to reflect the adoption of separate shipping descriptions for lithium ion batteries and lithium metal batteries.

Special Provision A51

Special provision A51 applies to the air transport of aircraft batteries, including lithium ion batteries. In this final rule, PHMSA is revising this special provision to reflect the adoption of separate shipping descriptions for lithium ion batteries and lithium metal batteries.

Special Provision A54

Special provision A54 requires a competent authority approval if the mass of a lithium battery exceeds the quantity limit specified in Column 9B for the HMT. In this final rule, PHMSA is revising this provision slightly to maintain consistency with the ICAO Technical Instructions.

Special Provision A55

Special provision A55 outlines conditions for the air transport of prototype lithium batteries. PHMSA is deleting special provision A55 and combining the transport provisions for low production runs with the transport provisions for prototype lithium batteries into § 173.185(e). See the detailed discussion of the revisions to § 173.185, below.

Special Provision A100

Special provision A100 prohibits the transport of lithium metal batteries aboard passenger carrying aircraft and permits the transport of up to 5kg of lithium ion batteries aboard passenger aircraft. In this final rule, PHMSA is adopting separate HMT entries for lithium metal batteries and lithium ion batteries. With the adoption of separate HMT entries for lithium metal and lithium ion batteries, this special provision is no longer necessary and is deleted.

Special Provision A101

Special provision A101 outlines the conditions and limitations on the air transport of lithium metal and lithium ion batteries packed with or contained in equipment. In this final rule, PHMSA is revising this special provision consistent with comparable provisions in the ICAO Technical Instructions applicable to lithium metal batteries packed with or contained in equipment.

Special Provision A103 And A104

Special provisions A103 and A104 prescribe quantity limits for lithium ion batteries packed with or contained in equipment. In this final rule, PHMSA is adopting separate HMT entries for lithium metal batteries and lithium ion batteries. With the adoption of separate HMT entries for lithium metal and lithium ion batteries, these special provisions are no longer necessary and are deleted.

C. Part 173

Section 173.185 Lithium Cells and Batteries

In § 173.185, PHMSA sets forth packaging requirements and certain conditional exceptions for the transport

of lithium batteries. As discussed above, other conditions and exceptions are located in special provisions in § 172.102. In the NPRM, PHMSA proposed to consolidate into a single section provisions for the packaging of lithium batteries primarily by relocating relevant requirements currently located in special provisions to § 173.185. Unless otherwise specified in this section, the hazard communication and training requirements located in part 172 of this subchapter will continue to apply to the transport of lithium cells and batteries.

Most commenters, including AHS, BAJ, COSTHA, UPS, and NAC supported the consolidation of lithium battery requirements into one section. Other commenters, including Delphi and NEMA supported the efforts to consolidate the lithium battery provisions into a single, easily referenced section, but suggested that this can only work if PHMSA harmonizes the HMR with international regulatory approaches.

In this final rule, PHMSA is consolidating into § 173.185 the general requirements for lithium batteries including UN design testing requirements, packaging requirements, and other transport conditions. Based on the provisions outlined in the ICAO Technical Instructions, the UN Model Regulation, and the IMDG Code, we are reorganizing this section by:

- Keeping the design testing and general safety requirements in paragraph (a) and adding a requirement to create and retain records of successful testing.
- Consolidating in paragraph (b) the packaging requirements for lithium cells and batteries, including cells or batteries packaged with, or contained in, equipment, when these items are shipped as Class 9 materials, including the provision in current paragraph (h) for shipping larger batteries (exceeding 12 kg (26.5 lbs in weight)).
- Placing exceptions for smaller lithium cells and batteries in paragraph (c).
- Revising paragraph (d), covering cells and batteries shipped for disposal or recycling, and consolidating in paragraph (e) provisions covering shipments of both low production runs and prototype cells or batteries.
- Adding provisions for shipping damaged, defective, or recalled batteries in paragraph (f).
- Moving to paragraph (g) the provision in current paragraph (f) for approval of transportation of a lithium cell or battery that does not comply with requirements in the HMR.

(a) Classification

In § 173.185(a), the HMR describe the requirements for transporting cells and batteries as a Class 9 material. These requirements include UN battery design testing, general battery design safety requirements, and packaging requirements. In the NPRM, we proposed to incorporate by reference the 5th revised edition of the UN Manual of Tests and Criteria and add (1) specific criteria for when testing of a “different design” would be required, and (2) a requirement for a manufacturer to maintain evidence of successful completion of required tests. We also sought comments on the benefits of requiring a quality mark, which would signify compliance with the UN battery design tests, to appear on the outside of the battery case.

- Test requirements and exemption for existing designs.

PHMSA adopted the fifth revised edition of the UN Manual of Tests and Criteria in the January 19, 2011 final rule (HM-215K) and Amendment 1 thereto in the January 7, 2013 final rule (HM-215L). Commenters including Saft and UPS supported adopting the updated testing standards in the 5th revised edition, but expressed concern that absent any exemption provision addressing cells and batteries qualified under prior versions of the UN tests, it would appear that all cell and battery designs would need to be retested.

PHMSA agrees with Saft’s recommendation to allow the continued transport of lithium cells and batteries tested under the prior versions of the UN tests. In this final rule, we are adding a reference to the 5th revised edition Amendment 1 of the UN Manual of Tests and Criteria and permit the continued transportation, without retesting, of lithium cell and battery designs that were tested in accordance with the version of the UN Manual of Tests and Criteria effective when the cell/battery was first transported.

In the 5th revised edition of the UN Manual of Tests and Criteria, Amendment 1, the criteria for batteries different from a tested type were revised to provide a non-exhaustive list of changes to a lithium battery or cell design that could be expected to “materially affect the test results” and require further testing. In the NPRM, PHMSA had proposed a separate list of changes that might lead to a failure of any of the tests would have constituted a design change requiring a manufacturer to subject a lithium battery design to the appropriate tests. The proposed changes would have been more conservative than those provisions

adopted in the 5th Revised edition of the UN Manual of Tests and Criteria and would have included: any change to (1) the anode, cathode, or electrolyte material; (2) protective devices including hardware or software; (3) the safety design of the cells, such as the safety vent; (4) the number of component cells; or (5) the connecting mode of the component cells.

PHMSA received mixed responses from commenters on this proposal. Some commenters supported the proposed changes, suggesting the examples provide useful clarification. Several comments from lithium battery and equipment manufacturers and other groups representing the battery industry and small business interests questioned the basis for proposed modifications to the design change criteria and the benefit of the specific criteria. They stated that changes that could influence safety vary and are not limited to the provided examples; conversely, certain changes on the proposed list may not always materially affect the test results. These commenters asked PHMSA to retain the design change requirements outlined in the UN Manual of Tests and Criteria.

In this final rule, we are not adopting the text proposed in the NPRM. The provisions outlined in the 5th Revised Amendment 1 of UN Manual of Tests and Criteria provide sufficient guidance to make testing determinations; PHMSA will continue to study this matter and stresses the importance of testing after any material modifications in the design or manufacturing.

- Test record requirements.

The UN Model Regulations and the ICAO Technical Instructions require lithium cells and batteries (including lithium cells and batteries packed with, or contained in, equipment) offered for transport to be manufactured under a quality management program (QMP) that includes: (1) A description of the organizational structure and responsibilities of personnel with regard to design and product quality; (2) the relevant inspection and test, quality control, quality assurance, and process operation instructions that will be used; (3) process controls that should include relevant activities to prevent and detect internal short circuit failure during manufacture of cells; (4) quality records, such as inspection reports, test data, calibration data, and certificates. Test data must be kept and made available to the appropriate national authority upon request; (5) management reviews to ensure the effective operation of the quality management program; (6) a process for control of documents and their revision; (7) a means for control of

cells or batteries that are not conforming to the type tested; (8) training programs and qualification procedures for relevant personnel; and (9) procedures to ensure there is no damage to the final product.

We are not adopting the requirement for lithium batteries to be manufactured in accordance with a quality management program in this final rule. We have not fully assessed the impact of requiring each cell and battery manufacturer to create and maintain such a program. However, since quality control in manufacturing is an important prerequisite to ensuring the safe transport of lithium batteries, we intend to initiate a separate rulemaking project to consider adopting additional portions of the QMP. Meanwhile, we encourage manufacturers to use good practices for ensuring consistency in manufacturing such as those found in the UN Model Regulations and the ICAO Technical Instructions.

At this time, we are adopting, as proposed and consistent with good quality management practices, a requirement for manufacturers to retain evidence of a successful completion of the UN design tests, for as long as they offer that battery design for transportation, and for one year thereafter. Manufacturers would be required to maintain this evidence in a readily accessible location at the principal place of business, for as long as the lithium batteries are offered for transportation in commerce, and for one year thereafter. Each person required to maintain this evidence must make it available at reasonable times and locations. This requirement would apply to all new cells and batteries manufactured after the effective date of this final rule. Commenters were generally supportive of this change.

UPS stated that a person could construe the proposed record-retention requirement as conditioning the length of the record-retention period upon the manufacturer’s offering of the lithium cell or battery for transportation, or such a transportation offering by any other person. Accordingly, we are adopting the suggestion of UPS to provide in § 173.185(a)(2) that “Each person who manufactures lithium cells or batteries must create a record of satisfactory completion of the testing prior to offering the lithium cell or battery for transport and must: (1) maintain this record for as long as that design is offered for transportation and for one year thereafter, and (2) make this record available to an authorized representative of the Federal, state or local government upon request.

NEMA and PRBA questioned PHMSA's assumptions and analysis on information collection costs for the creation of battery design testing records. NEMA stated that a design drawing for a simple battery pack adequate for use in any reasonable quality system takes 8–16 hours of a skilled draftsman, along with a few hours of engineering support, and both types of employees earn more than \$25 per hour. The commenter further stated that even the smallest assembler has more than 10 designs and major companies have hundreds of designs. However, this final rule does not require a lithium battery manufacturer to generate engineering drawings or extensive documentation. While the commenter notes that a battery assembler may have various designs, the commenter did not elaborate on whether each of these designs would require separate testing and documentation in accordance with the requirements for the UN Manual of Tests and Criteria.

This final rule requires manufacturers to retain evidence of successful completion of the required tests, for as long as they manufacture that battery design and for one year thereafter. This evidence must also be made available to an authorized representative of the federal, State or local government, upon request. PHMSA is adjusting its information collection burdens for the creation and retention of records of completion of design testing requirements. PHMSA estimates the burden of generating and retaining documentation that certifies compliance with the UN Manual of Tests and Criteria based upon an assumption that there are 110 active lithium battery manufacturers, which produce an average of 10 designs each, and that each design requires approximately 30 minutes of design records to be generated and documented. This produces an industry total of 550 hours.

- General safety requirements.

The HMR require lithium batteries to be equipped with certain safety features such as safety venting devices and diodes or fuses if a battery contains cells or series of cells that are connected in parallel. These provisions (currently in § 173.185(a)(2) and (a)(3)) are being combined into a single sub-paragraph (a)(3).

- Marking of Watt-hour rating on lithium ion batteries.

We are adding a requirement in paragraph (c)(1)(i) that each small lithium ion battery manufactured after December 31, 2015, to be marked with the Watt-hour rating on the outside case. This action is consistent with

requirements found in the UN Model Regulations, the ICAO Technical Instructions and the IMDG Code since 2009. Incorporating this provision into the HMR ensures greater consistency between the HMR and the international regulatory standards. As previously mentioned, this requirement has been in effect in the UN Model Regulations, the ICAO Technical Instructions and the IMDG code for several years, we do not anticipate substantial impact in complying with this requirement.

- Marking cells and batteries to indicate successful testing.

In the NPRM, PHMSA stated that it was considering requiring the presence of a visible quality mark on the outside case of each cell or battery to signify successful completion of the required lithium battery design tests in a readily recognizable manner. The proposal was intended to promote knowledge of the UN tests throughout the world and provide downstream shippers with a straightforward means of identifying lithium batteries that meet applicable UN testing standards.

PHMSA received supportive comments from ALPA, TDD, and air carriers stating this would provide useful information for shippers to determine if cells and batteries were properly tested prior to offering them into transport. Most commenters questioned the benefit of an additional mark on batteries already marked in compliance with other bodies such as Underwriters Laboratory. Several other commenters stated that the presence of an additional symbol in no way affects the likelihood that a particular battery complies with the UN testing provisions, and posed problems since the mark could be counterfeited. Several air carriers commented that carriers should not be expected to look inside packages or devices to see if a mark is present. Until a universally recognized quality mark is established, and the obstacles to implementing such a system are overcome, PHMSA will not propose to require such a mark.

- Liquid cathode cells.

PHMSA also proposed to retain the longstanding prohibition in current § 173.185(a)(6) forbidding the transport of certain liquid cathode cells when discharged to less than 2 volts or 2/3 the voltage of the fully charged cell, except when transported for disposal or recycling. Saft states that this prohibition does not exist in the UN Model Regulations or the IMDG Code. It states the ICAO Dangerous Goods Panel (DGP) removed this provision from the ICAO Technical Instructions effective January 1, 2011 based on improvements to lithium battery manufacturing and

the addition of a forced discharge test to the UN design testing requirements that eliminate the need for this now outdated provision. We agree that there is no longer any need for this provision, and it is being removed.

(b) Packaging of Class 9 Materials

The HMR currently require lithium cells and batteries to be packed in inner packagings in such a manner as to prevent short circuits, including movement which could lead to short circuits. These inner packaging must be placed in an outer package conforming to the requirements of part 178, subparts L and M, at the Packing Group II performance level. The HMR also require that lithium cells or batteries packed with equipment and lithium cells or batteries contained in equipment must be: (1) Of a design that meets the UN tests; (2) packed to prevent short circuits; and (3) packed in UN-performance packagings and the equipment and the packaged cells or batteries contained in a strong outer package.

In the NPRM, PHMSA proposed to continue these requirements but consolidate in paragraph (b) all the packaging requirements for lithium cells and batteries shipped as a Class 9 material, including cells and batteries packed with, or contained in, equipment. Three commenters, DGAC, IATA, and COSTHA, appear to have interpreted the proposals in the NPRM to except lithium batteries packed with equipment from the specification packaging requirements not covered by an exception. This was not our intent. Lithium batteries packed with equipment that otherwise do not meet the criteria for an exception must be placed into a suitable UN standard packaging that meets the Packing Group II performance level consistent with the UN Model Regulations, the IMDG Code, and ICAO Technical Instructions.

The HMR also currently require lithium battery powered equipment to be placed into a strong outer packaging that is waterproof or is made waterproof by nature of its construction. NAM and Delphi suggested removing this requirement. They state that waterproof packaging requirements for equipment containing lithium ion or lithium metal batteries regardless of mode of transportation (air, rail, highway, and water) are onerous and inconsistent with the UN Model Regulations, the ICAO Technical Instructions, and the IMDG Code. Covidien requests clarification of the word "waterproof" and requests that PHMSA acknowledge in its review that the concept of "waterproof" should be a risk-based

determination tied to international approaches, rather than an absolute concept. Since this requirement does not appear in the UN Model Regulations, the ICAO Technical Instructions or the IMDG Code, and there is no clear basis for this requirement in the HMR, PHMSA is removing this requirement.

Soft states the requirement that lithium batteries be packed in combination packages that meet the packing group II performance standards appears inconsistent with the provision in current § 173.185(g) allowing batteries that exceed 12 kg gross weight and are equipped with a strong, impact-resistant, outer casing currently to be packaged in a strong outer packaging in a protective enclosure. For clarity, PHMSA is moving this separate packaging provision to paragraph (b)(5) under the Class 9 packaging requirements.

In this final rule, PHMSA is harmonizing the packaging requirements applicable to lithium batteries packed with equipment and lithium batteries contained in equipment with the UN Model Regulations, the ICAO Technical Instructions and the IMDG Code. When packed with equipment, the lithium battery must be placed into an authorized package that meets the Packing Group II performance level, or the battery must be placed into a suitable inner packaging then placed with the equipment into a suitable outer package that meets the Packing Group II performance level. The packaging requirements for lithium cells and batteries, including lithium cells and batteries packed with, or contained in, equipment, are contained in a single paragraph (b). Paragraph (b)(1) includes a reference to the general packaging requirements in §§ 173.24 and 173.24a applicable to all hazardous materials, and a definition of the term “equipment,” as it is used in this section. Paragraph (b)(2) includes provisions specific to lithium batteries such as packaging to prevent short circuits, sparks, or the generation of a dangerous amount of heat movement within the package. Paragraph (b)(3) sets forth packaging requirements for lithium cells and batteries not contained in equipment (i.e., packages of batteries, and batteries packed with equipment). These are specific requirements applicable to only these configurations including a requirement that inner packaging completely enclose the cell or battery and the authorized UN outer packagings. Paragraph (b)(4) includes the unique additional requirements applicable to lithium batteries contained

in equipment, including a requirement that equipment be protected from accidental activation and providing an exception from UN packaging. Paragraph (b)(5) includes a provision for packaging lithium batteries and assemblies of batteries with a gross weight greater than 12 kg (26.5 lbs) that employ a strong impact resistant outer casing which was formerly located in § 173.185(g).

(c) Exceptions

As discussed above, special provisions 188 and 189 currently provide provisions for “small” and (for rail or highway only) “medium” lithium metal and lithium ion cells and batteries, respectively, provided they meet the design tests outlined in the UN Manual of Tests and Criteria, and are packed in a strong outer package in a manner that prevents short circuits and damage.⁵ Each package containing more than 24 lithium cells or 12 lithium batteries must: (1) Be marked to indicate that it contains lithium batteries and that special procedures are to be followed if the package is known to be damaged; (2) be accompanied by a document indicating that the package contains lithium batteries and that special procedures are to be followed if the package is known to be damaged; (3) weigh no more than 30 kilograms; and (4) be capable of withstanding a 1.2 meter drop test, in any orientation, without shifting of the contents that would allow short-circuiting or release of package contents.

In the NPRM, PHMSA proposed to:

- Create a new exception for extremely small batteries with very low energy (i.e. 0.3 grams lithium content for lithium metal or 3.7 Wh for lithium ion) when packed with or contained in equipment. We additionally requested comment on an exception for lithium batteries shipped at a reduced state of charge. PHMSA based the 0.3 gram or 3.7 Wh thresholds on the energy levels found in common coin or button cells.
- Eliminate the current exceptions for the air transport of small lithium cells and batteries, including small cells and batteries packed with or contained in equipment. Thus when transported by air, all lithium cells and batteries would be regulated in the same manner regardless of their size;

⁵ A “small” lithium cell or battery may not contain more than 1 gram per lithium metal per cell, 2 grams lithium metal battery or 1.5 grams ELC per lithium ion cell, 8 grams ELC per lithium ion battery. A “medium” lithium cell or battery may only metal lithium 1 gram and 5 grams per cell and between 5 grams and 25 grams per battery or, for a lithium ion cell or battery, ELC between 1.5 grams and 5 grams per lithium ion cell and ELC between 8 grams and 25 grams.

- Restrict exceptions for surface transport consistent with the UN Model Regulations and the IMDG Code.

- Highway, rail and vessel shipments of “small” cells/batteries would be excepted from shipping paper, marking and labeling requirements;

- Shipments of “medium” cells/batteries would be restricted to highway and rail only;

- Packages containing more than 8 lithium cells or 2 lithium batteries would be subject to package marks indicating presence of lithium batteries and special procedures to follow if package damaged, an accompanying shipping document, a 1.2 meter drop test and 30 kg per package weight limit;

Recent revisions to the ICAO Technical Instructions include provisions for extremely small lithium metal cells and batteries containing less than 0.3 grams of lithium metal, lithium ion cells and batteries less than 2.7 Wh, and an exception from button cells installed in equipment, such as circuit boards. We also expect that implantable medical devices would be covered under this exception. PHMSA is revising the HMR consistent with these exceptions.

Other changes that became effective in the 2013–2014 ICAO Technical Instructions concerned small lithium cells and batteries that by virtue of their size, were previously afforded exceptions from most requirements. The revisions now effective in the ICAO Technical Instructions require: (1) Each package that contains more than 8 small lithium cells or two small lithium batteries display a Class 9 hazard warning label in addition to the lithium battery handling label; (2) shipping papers accompany the shipment, unless the shipper provides alternative written documentation describing the shipment; (3) formalized employee training and testing; (4) carrier acceptance checks; and (5) pilot notification.

ACCO, PRBA, and BAJ stated that the very low threshold for excepting batteries (0.3 g or 3.7 Wh) would provide little to no assistance to shippers utilizing single cell batteries such as cellular phones and other consumer electronic devices that generally fall in the range of 4–6 Wh. Alaska Airlines, A4A, NAC and NEMA questioned the basis for the proposed battery size limits and raised concern regarding the effects of proposing additional requirements not contained in the ICAO Technical Instructions. Other commenters stated that the exception is unnecessarily restrictive. Garmin considers devices containing lithium batteries such as cellular phones and MP3 players as posing no danger of

accidental external short circuiting. The commenter stated that the physical structure of these devices, the custom packaging for spare batteries, and the recessed nature of battery terminals all effectively mitigate short circuit hazards in transport. Digital Europe requests PHMSA align with the ICAO Technical Instructions that except lithium button cells installed in equipment from certain marking requirements.

IFALPA, ALPA, NFPA, and NTSB supported PHMSA's original proposal to otherwise eliminate regulatory exceptions for lithium batteries in air transportation, including the introduction of requirements for hazard labeling, packaging, training, and the inclusion of lithium battery shipments on the notice to the pilot in command. These commenters support subjecting all lithium batteries to the same requirements, regardless of size. They stated that this will improve hazard communication, reduce battery incidents through enhanced training, and provide pilots with knowledge of the size, location, and the quantity of lithium battery shipments that will assist flight crew decision making during an in-flight emergency. NFPA stated that the proposed measures included in the NPRM provide more complete information, in a more consistent manner, for access by the transporter as well as the emergency responders, when necessary. In their comments to the NPRM, the NTSB stated that cargo shipments of small lithium batteries should be subject to the same packaging and identification requirements that apply to medium and large lithium batteries to alert package handlers to exercise greater care when loading and unloading packages containing them. ALPA stated that hazardous materials have been safely transported for decades under the HMR, and bringing lithium batteries fully into this regulatory scheme would provide significant safety benefits. ALPA goes on to say that by eliminating the regulatory exception for lithium battery shipments, handlers will separate packages containing lithium batteries from general freight, reducing the possibility of inadvertent damage. These shipments would also be subject to an acceptance check by airline personnel prior to placement in air transportation, including inspection of the package to detect damaged or improperly prepared packages.

Most other commenters opposed PHMSA's proposal to eliminate the regulatory exceptions for the air transport of lithium batteries. AIAM, COSTHA, DGM, EPBA, and IATA cited confusion and increased complexity

that would result from different requirements. ATA, Alaska Airlines, CEA, Horizon Air, Korea, Panasonic, PRBA, and Saft did not accept PHMSA's incident analysis as support for eliminating the regulatory exceptions for lithium batteries. These commenters stated they are not aware of any safety incidents involving the air transport of properly packaged batteries, or batteries in compliance with existing regulations. CIPA and Fedco added that new regulations will not enhance compliance if shippers ignore them. TIACA stated that the incidents cited for reasons of non-compliance raises calls for better enforcement, rather than sweeping new regulations. The SBA recommended that PHMSA conduct further outreach to the regulated community to enhance dialogue, promote safety, and ensure harmonization.

Saft, Southwest, and others stated that PHMSA's decision to propose different requirements for lithium batteries and lithium batteries packed with, or contained in, equipment than those applied internationally would actually detract from safety, because these differences would create confusion and excessively complicate an already complex set of regulations that apply to lithium battery shipments. SBA and PRBA stated that the proposed rules would create conflicting standards and require significant supply chain redesigns. Lifescan, NAM, UPS, and others cite multimodal difficulties when the U.S. HMR conflict with the other published regulations. They stated that the provisions in the NPRM will cause such packages and devices to be non-compliant upon entering the United States.

Other commenters stated that the imposition of more restrictive U.S. requirements compared to the ICAO Technical Instructions would have far-reaching adverse economic consequences. These commenters stated that the elimination of the current exceptions would result in burdensome administrative procedures, higher transportation costs, and longer transportation time due to import and export barriers, disruptions to air freight, and increased costs of packaging, transport, and storage.

Some commenters cited the impacts of this proposal on their industry sectors medical equipment and information technology. At the March 5, 2010, public meeting, as well as in written comments, they suggested that various aspects of the NPRM would inappropriately subject medical devices to the HMR and requested that PHMSA except finished medical devices from

the HMR. The commenters stated that the NPRM requirements would create severe disruptions to current shipping practices and could threaten patient access to life-saving and life-enhancing medical devices. These commenters further stressed the difference between implantable medical devices regulated by the U.S. Food and Drug Administration (FDA) and typical consumer products. They stated that medical devices are already subject to additional controls including registration of the manufacturing facilities, quality system requirements, and post market surveillance and reporting. Devices that pose a higher risk to a patient such as implantable medical devices undergo an extensive FDA pre-market approval process to establish reasonable assurance of safety and effectiveness of the device.

NAM stated that the NPRM is inconsistent with other national policy goals because the rule would make the transport of large, advanced batteries used for electric and hybrid vehicles and domestic energy exploration more difficult and expensive. AT&T suggested that, if PHMSA adopts the proposed rules, the wireless business would have to make a dramatic shift to surface transport, which would not only delay the delivery of products and services to enterprise business customers, government agencies, and consumers, but also, more fundamentally, slow the velocity of competition and innovation. Moreover, customer demands would be met not only more slowly, but also unevenly. NetApp asserted that PHMSA did not adequately assess the effects of the NPRM on U.S. companies that manufacture and ship large equipment containing lithium ion batteries. NetApp stated that the proposed regulation would significantly impede their ability to meet customers' expedited delivery requirements and place them at a disadvantage relative to foreign manufacturers.

NEMA strongly recommended that PHMSA and its regulatory partners take sufficient time to recognize the additional protection from short circuit or other malfunction that equipment and additional packaging provide to lithium batteries. NEMA suggested that PHMSA should except equipment and devices containing or packed with lithium batteries from full regulation under Class 9. RBRC stated that the limit on the number of batteries that can be shipped in a single package with a piece of equipment powered by lithium ion batteries (proposed subsections 173.185 (b) and (c))—would preclude the collection of used cellular phones in

the same boxes with used lithium ion batteries.

In the NPRM, PHMSA proposed specific requirements for extremely small batteries with very low energy (i.e. 0.3 grams lithium content for lithium metal or 3.7 Wh for lithium ion) when packed with or contained in equipment.

Trucking, Saft, Energizer, and the RBRC strongly opposed the proposed elimination of the exception from the requirements of subpart H ("Training") of part 172 of the HMR for both "small" and "medium" batteries, regardless of the mode of transport. The commenters state that removal of these exceptions will result in a very significant increase in the costs associated with the supply of lithium cells and batteries for many important applications—including medical, military, security equipment, personal phones, computers, and other electronic devices. GE Corporation (GE) requested that, if PHMSA does impose training requirements on hazmat employees transporting small lithium cells and batteries by ground, they be similar to those outlined in the ICAO Technical Instructions for batteries since, in most instances, lithium batteries will be the only type of hazardous material shipped by the employees subject to these requirements. In this final rule, PHMSA is not imposing specific training requirements on shippers offering lithium batteries and battery powered devices for surface transport that meet all of the applicable conditions of § 173.185(c).

In this final rule, PHMSA will not eliminate provisions for the air transport of small cells and batteries as originally proposed. Instead, we will adopt the provisions outlined in the UN Model Regulations, the ICAO Technical Instructions and the IMDG Code that permit the transport of a up to 8 lithium cells or 2 small lithium batteries (less than 1 gram per lithium metal cell or 2 grams per lithium metal battery and 20 Wh per lithium ion cell or 100 Wh per lithium ion battery) including small lithium batteries packed with, or contained in, equipment. We are maintaining the current prohibition from transporting lithium metal cells or batteries aboard passenger carrying aircraft (regardless of size) when the cells and batteries are not packed with or contained in equipment.

We will also continue to provide exceptions from the shipping paper, marking, labeling, emergency response information, and training requirements for the transport of small and medium sized batteries by highway and rail only. Packages containing lithium cells and batteries that meet the conditions of this

exception must be marked "LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD AIRCRAFT AND VESSEL." UPS suggests text markings on packages are variable and provide limited effectiveness. The commenter suggests a clear graphic marking will assist in overcoming any English-language barriers that may be faced by personnel loading aircraft or aircraft containers, especially when the shipments involved are known to move very commonly in international commerce. KITA, KEA, KORBA suggested that the proposed mark would create confusion and further suggested that PHMSA permit the air transport of lithium batteries consistent with the ICAO Technical Instructions. NEMA stated that the existing international labeling requirements, combined with those being proposed, would cause confusion in multi-modal transport as well as cross-border ground transport. The commenter further states that since these products are transported several times, by several different modes, and cross international borders during their journey, consistent international regulatory approaches ensure compatibility and that transportation risks are properly managed.

PHMSA does not expect the text mark required on packages as a condition of this exception will cause confusion in multimodal or international transport because this marking would apply only in limited circumstances. The HMR would only require the additional text marking for medium-sized lithium cells and batteries transported under the exceptions permitted for highway and rail transport.

In the preamble to the NPRM, PHMSA noted that the ICAO Technical Instructions require certain packages to display a lithium battery handling label.⁶ This label conveys certain information including: The presence of lithium batteries; the fact that a flammability hazard exists if damaged; instructions to package handlers in case a package is damaged; and a telephone number for additional information. In the NPRM, PHMSA noted that the ICAO lithium battery handling label conveys this information, and, while the HMR currently do not require the use of the lithium battery handling label we permit its display because it conveys the information required to appear on packages containing lithium batteries. PRBA states that PHMSA's permission for shippers to utilize the lithium

battery handling label is misguided and would cause greater confusion. PRBA states the lithium battery handling label was adopted by ICAO to distinguish between shipments of fully-regulated lithium batteries and shipments of lithium batteries offered under the exceptions found in Packing Instructions 965–970 of the ICAO Technical Instructions. PRBA contends that if PHMSA includes a provision in the HMR that "authorizes" the use of the lithium battery handling label, it would only further confuse shippers of these products and result in greater non-compliance.

The HMR require certain information to appear on packages containing lithium batteries offered for transportation under the various exceptions. This required information includes an indication of the presence of lithium batteries and the special procedures that should be followed if the package is damaged. PHMSA requires the display of the lithium battery handling label for shipments transported by aircraft, but still permits voluntary use of this label by all modes on the basis that this label conveys the information required by the HMR.

We note that the ICAO Technical Instructions and the IMDG code differ in the quantity limits for small lithium batteries. Specifically, the ICAO Technical Instructions limits a package to 8 small lithium cells or 2 small lithium batteries, but does not impose a package mass limit. Conversely, the UN Model Regulations and the IMDG code do not limit the number of cells or batteries that can be contained in the package, but limits each package to 30 kg gross weight. We do not expect this difference between in quantity limits will pose significant difficulties because the cell and battery size and quantity limit in the ICAO Technical Instructions effectively limit the package weight in line with the surface modes (i.e. a package of lithium cells or batteries properly packaged in accordance with the packing instruction 965 or 968 of the ICAO Technical Instructions will also meet the provisions of the IMDG Code special provision 188 including the 30 kg gross weight limit).

In the NPRM, PHMSA requested comment on whether it should adopt an exception for batteries shipped at a reduced state of charge. ALPA recognizes that the energy in a lithium ion battery and the intensity of a fire involving that battery directly relates to its state of charge and a lower state of charge reduces the risk posed by a battery in transportation. However, ALPA expressed concern that incorporating state of charge

⁶ The 2013–2014 ICAO Technical Instructions refer to a "lithium battery handling label." In this final rule, we use the phrase "lithium battery handling marking" to distinguish it from hazard warning labels described in Part 172, Subpart E.

requirements in the HMR will be nearly impossible to verify or enforce. CERC stated that an exception for a reduced state of charge could not feasibly work for retailers and the millions of annual shipments of products to and from service centers. Additional commenters stated that it would be impossible for used battery collection programs to know the state of charge of each battery placed in collection boxes used at schools, libraries, and federal and state buildings throughout the U.S. Conversely, Quallion supported a limitation on state of charge for some lithium ion cells and batteries shipped by air stating that shipping at a lower state of charge further reduces the already-low risk of a fire in the event of significant damage to properly packaged products. PRBA states that such a limitation should not apply to batteries and batteries packed with, or contained in, equipment shipped for military or medical applications or batteries collected and shipped for recycling. When batteries are packed with, or contained in equipment, the limited additional benefit of mandatory reduced charge is overcome by the need for these products to work immediately when they reach their final destination. Due to its limited applicability and difficulty to verify, PHMSA will not adopt an exception based on a limited state of charge. However, when practical, PHMSA encourages shippers and manufacturers to utilize all appropriate methods, including shipping batteries at a reduced state of charge to help mitigate the hazards associated with transporting lithium batteries.

PHMSA received several comments requesting exceptions from the HMR based on battery chemistry or end use. For example, SureFire recommended that PHMSA include exceptions for purposes of military, first responder, medical, and other critical applications. Control Technology Inc. stated that certain chemistries such as lithium iron phosphate (LiFePO₄) are much safer than competing technologies, which pose far greater fire risks. Energizer requested that PHMSA except lithium iron disulfide (LiFeS₂) batteries from the HMR when the batteries meet the existing requirements. This commenter cites a lack of incidents and recognition of overall safety and quality. Panasonic suggested that PHMSA except lithium manganese dioxide CR cells and lithium carbon monofluoride BR cells from the Class 9 shipping requirements when the cells contain less than 1 gram lithium metal and are proven to have satisfactorily completed the UN tests and are properly packaged. The

commenter added that these batteries are produced on automated lines in the U.S., Japan, and Indonesia and incorporate numerous safety features to ensure they are safe under abuse conditions. The same commenter further stated that these batteries are used in hundreds of applications ranging from acting as the primary power source to providing power for memory back-up. While PHMSA appreciates the extensive work already completed to create safer batteries, the fact remains that lithium batteries still pose chemical and electrical hazards. While certain chemistries may possess a greater resistance to abuse, we do not agree that it is appropriate to create exceptions based on specific chemistries or applications.

(d) Lithium Cells and Batteries Shipped for Disposal or Recycling

In the NPRM PHMSA proposed to continue the exception currently in § 173.185(d) from the UN design testing requirements and the UN specification packaging requirements when lithium cells or batteries are transported by motor vehicle for disposal or recycling. Shipments of lithium batteries would continue to be subject to all other applicable provisions of the HMR.

GRC expressed concern that the proposed revisions do not exclude the responsibility for hazardous materials training for their suppliers. GRC stated that training in accordance with part 172, subpart H would be virtually impossible, given the nature of their participating organizations and the number of collection sites that include non-profits, schools, retailers, community groups, and businesses. CEA contended that the proposals in the NPRM will ultimately act as a disincentive for consumers to recycle responsibly. RBRC stated that, for this rule to be successful there must be a specific provision dealing with collection for recycling programs that recognizes the simple fact that most used batteries collected are, by their very nature, in a low state of charge.

PHMSA agrees with the commenters that the nature of the battery recycling and disposal process very often make compliance with all HMR requirements, including hazmat employee training, difficult and, in many cases, unnecessary. However, PHMSA remains concerned that uneven compliance with basic safety requirements, such as short circuit and damage protection of lithium batteries, can lead to transportation incidents as an increasing number of lithium and other high energy batteries enter the waste and recycling stream. At the same time, PHMSA recognizes the

role that battery recycling and disposal industries play in environmental stewardship.

In this final rule, PHMSA continues to provide exceptions from the UN design testing requirements and the UN packaging requirements when lithium cells and batteries (including lithium cells or batteries contained in equipment) are transported by motor vehicle for disposal or recycling. Further, we are excepting offerors and carriers from the requirements for part 172, subparts C through H (shipping papers, marking, labeling, placarding, emergency response information and training) for appropriately packaged small and medium-sized lithium batteries when such batteries are offered for transport by motor vehicle to a permitted storage facility or for the purposes of recycling.

(e) Low Production Runs and Prototypes

The HMR have separate but similar provisions for low production runs and prototype lithium batteries in § 172.102(c), special provision 29, and § 173.185(e), respectively. Both of these provisions except lithium batteries from the UN battery design testing requirements under certain conditions. As proposed in the NPRM, PHMSA is combining in § 173.185(e) the conditions for the transport of low production runs and prototype lithium batteries that have not been subjected to the appropriate UN design tests, consistent with the UN Model Regulations.

Johnson Controls and Saft supported the exceptions for transporting “prototype” or “low production runs” of lithium cells or batteries. In particular, Saft welcomed the proposed expansion of the current text—which covers only prototypes—to also address the transport of cells and batteries produced in low production runs as such action is consistent with UN special provision 310. However, Saft asked PHMSA to authorize transport by vessel consistent with the provisions of IMDG Code special provision 310. PHMSA agrees with the commenter. Special provision 310 of the IMDG code authorizes the vessel transport of low production runs consisting of not more than 100 cells or batteries, or to prototypes.

Saft also proposed adding a new paragraph to authorize non-specification packaging for batteries employing a strong, impact-resistant outer casing and exceeding a gross weight of 12 kg (26.5 pounds), and assemblies of such batteries when transported by highway and rail. It stated that many of the newer prototype or low production lithium

batteries are of such a size that use of UN standard packagings as would otherwise be required would be impractical for the same reasons that use of such packaging is impracticable for UN-tested batteries of similar size.

PHMSA agrees such a provision would facilitate the transport of large, robust lithium batteries without sacrificing safety. In this final rule, we are adding a provision to authorize non-specification packaging for low production and prototype lithium metal and lithium ion batteries employing a strong, impact-resistant outer casing and exceeding a gross weight of 12 kg (26.5 pounds), and assemblies of such batteries. In this final rule PHMSA authorizes such packaging for transport by highway, rail and vessel consistent with special provision 310 of the IMDG Code. PHMSA continues to forbid transport of lithium batteries in these non-specification packages by passenger-carrying aircraft and only permits transport by cargo air when approved by the Associate Administrator prior to transport.

(f) Damaged Defective or Recalled Batteries

Lithium batteries and devices are returned to manufacturers and retail outlets for a variety of reasons including product returns, warranty fulfillment, repair, failure during field testing, or a manufacturer recall. The HMR do not currently contain provisions for transporting batteries subject to a manufacturer's recall or that are damaged and potentially dangerous. Based on previously developed guidance material and competent authority approvals, PHMSA will require lithium batteries that have been damaged, identified as being defective, or are otherwise being returned to the manufacturer for safety reasons, to be packaged in combination packages, surrounded by non-conductive cushioning material, and transported by highway or rail only. PHMSA and the FAA would address situations requiring air transport on a case-by-case basis by Approval.

Most commenters generally supported these proposals. However, they expressed concern that the words "damaged" or "defective" may be subject to misinterpretation. For example, scratches or other cosmetic damage to a battery casing, or, for large batteries, damage to external structural features such as bolt-down lugs, would not constitute damage that affects the safety of the battery in transport. PRBA suggested clarifying language stating that damaged, defective, or recalled batteries which do not have the

potential of producing a dangerous evolution of heat, fire or short circuit are not subject to the paragraph. PRBA stated that this would allow companies to ship batteries by air that simply are not working to specification, but which pose no additional safety risk in transport. PRBA states this option is necessary for many reasons, but is most important for batteries designed for use in medical and military applications. For example, if a battery is not working to specifications in such lifesaving applications as defibrillators, it is critically important for the battery to be quickly returned to the manufacturer for analysis. Special provision A154 in the ICAO Technical Instructions states that batteries are prohibited from transport by aircraft only to the extent that any damage or defect causes the battery to "have the potential of producing a dangerous evolution of heat, fire or short circuit."

UPS also supported PHMSA's proposal, but noted that the provision does not appear to provide a viable means of transport for residents of Alaska, Hawaii, Puerto Rico and others not accessible by the highway and rail system. Horizon Air and Rep. Don Young request exceptions for communities such as those in Alaska not accessible by surface transportation. These commenters suggested that PHMSA add a provision stating that damaged defective or recalled batteries are not permitted for transportation by passenger-carrying aircraft and may be transported by cargo aircraft only if approved by the Associate Administrator prior to transportation. NITL, NEMA and others stated that an option to transport these batteries by cargo vessel is necessary to enable returns from overseas if the air mode is not available. Several other commenters stated that failure to allow a mode that will enable returns from overseas will be counterproductive, since it will prevent battery companies from fully investigating and analyzing product defects or failures.

In response to these comments, PHMSA is authorizing the transport of damaged, defective or recalled cells or batteries by highway, rail, or vessel when the batteries are packaged in specification packagings and each battery is individually placed into inner packagings surrounded by cushioning material that is non-combustible, and non-conductive. PHMSA is adopting language consistent with the ICAO Technical Instructions that prohibit the air transport of lithium cells or batteries that are subject to a safety recall or batteries that have been damaged and have the potential of producing a

dangerous amount of heat or fire. PHMSA will evaluate the need to transport such cells or batteries by aircraft on a case-by-case basis by Approval.

Section 173.219 Life-Saving Appliances

Section 173.219 requires life-saving appliances containing lithium batteries to be transported in accordance with § 173.185 of the HMR and special provisions 188, 189, A101, A103 and A104 as applicable. PHMSA did not receive comments specific to the transport of life-saving appliances. In this final rule, PHMSA is revising this section consistent with other changes in this final rule. Lithium batteries packed with, or contained in, life-saving appliances must meet the applicable requirements of § 173.185 and special provisions A54 and A101.

Section 173.220 Vehicles

Section 173.220 contains conditions and exceptions applicable to the transport of vehicles and machinery, including those powered by lithium batteries. In the NPRM, PHMSA proposed to except prototype lithium batteries from the UN design testing requirements when these vehicles are transported by highway for product testing. The batteries would be required to be securely installed in the vehicle. Commenters supported this proposal and no objections were raised. PHMSA is adopting this exception as proposed.

D. Part 175

Section 175.8 Exceptions for Operator Equipment and Items of Replacement

In § 175.8, PHMSA provides exceptions for operator equipment and items of replacement. In the NPRM, PHMSA proposed to modify § 175.8 to permit airlines to carry additional items approved by the FAA Administrator for use aboard the aircraft. This proposal was in response to the December 15, 2008, petition for rulemaking (P-1533) from A4A and the RAA. The petition requested that PHMSA amend the HMR to permit airlines to carry a limited number of small lithium batteries in the aircraft cabin in a constant state of readiness with adequate backup power for the duration of the flight. PHMSA agreed with airlines' need to maintain and use various types of equipment in the cabin, which are increasingly powered by lithium batteries.

Commenters generally supported the proposals to permit airlines to carry lithium batteries in the cabin to power devices such as electronic flight bags, onboard medical monitoring devices,

and credit card readers. Southwest supported the proposed revision of § 175.8 for operator equipment and items of replacement, but suggested that the regulation should clearly identify which branch of the FAA will act on a request for an approval (Certificate Management Office, Flight Standards, Hazmat Branch Managers, etc.), and that the approval process should provide for review and feedback in a timely and consistent manner. Three commenters requested that PHMSA clarify the wording “Items containing hazardous material” and suggested that this wording would preclude spare lithium batteries for required devices. On September 23, 2009, the FAA published a document *Information for Operators* (InFO) that discusses the appropriate regulations applicable to the operation of portable electronic devices aboard aircraft. This InFO is available through the FAA at the following URL: http://www.faa.gov/other_visit/aviation_industry/airline_operators/airline_safety.

In response to the commenters’ PHMSA is revising the proposed § 175.8(a)(4) to read “hazardous materials used by the operator aboard the aircraft when approved by the Administrator of the Federal Aviation Administration.” This will permit operators to carry hazardous material used by the flight crew as appropriate, subject to approval by the Administrator of the FAA.

Section 175.10 Exceptions for Passengers

In § 175.10, the HMR provide conditions and exceptions for the transport of certain hazardous materials when carried by aircraft passengers or crewmembers in checked and carry-on baggage. In the NPRM, PHMSA proposed to require lithium batteries carried by a passenger or a crewmember in checked or carry-on baggage to be of a type proven to meet each of the appropriate tests outlined in the UN Manual of Tests and Criteria.

PRBA supported PHMSA’s proposal. DGAC stated that, while it would expect cells and batteries would meet the UN testing requirements, it wonders how passengers would actually know whether their batteries were tested. In addition, it questions how such a requirement would apply to passengers arriving from outside the United States. The 2013–2014 ICAO Technical Instructions already include the requirement for the manufacturer to test lithium cells and batteries, and all lithium batteries must already be of a design that meets each test in the UN Manual of Tests and Criteria prior to

being offered for transportation.

Accordingly, we do not anticipate any adverse impact to harmonizing the provisions of the HMR with the provisions of the ICAO Technical Instructions at this point.

NFDA asked PHMSA to insert the words “living or deceased” before the word “humans” in § 175.10(a)(3), in order to clarify that implanted medical devices in a deceased human body being transported by an air carrier falls under the exception currently available for living humans. The provisions in § 175.10(a)(3) applicable to implanted medical devices in humans or animals does not specify the condition of the human or animal. Thus this provision already permits implanted medical devices regardless of whether the human or animal is alive or deceased.

PRBA and others note the HMR currently authorize a passenger to carry lithium ion batteries up to 300 Watt-hours, but the ICAO Technical Instructions limit a passenger to carry lithium ion batteries up to 160 Watt-hours and requires authorization of the airline if the battery is over 100 Watt-hours. The commenters state this should be changed to harmonize with the ICAO Technical Instructions. We agree and in this final rule we are revising § 175.10 to state, when approved by the air operator, up to two individually protected spare lithium ion batteries per person having a Watt-hour rating greater than 100 Wh, but not greater than 160 Wh, may be carried in (a) carry-on baggage, or (b) equipment in either checked or carry-on baggage.

PRBA and NEMA also noted that PHMSA also has included a provision that appears to prohibit spare “dry cells and batteries” (e.g., alkaline, nickel cadmium, nickel metal hydride) from placement in checked baggage. NEMA opposed any such prohibition and states that non-lithium dry cell batteries, even when new and deliberately shorted in large quantities cannot produce dangerous levels of heat. PRBA asked PHMSA to clarify whether we intended to prohibit dry cell batteries from checked baggage. They state this would be an impossible provision to enforce considering the millions of alkaline batteries purchased by consumers every year in the U.S. and is unnecessary in light of the battery’s low voltage. PHMSA did not intend to limit the ability of passengers to carry spare non-lithium dry cell batteries to carry-on baggage. In this final rule, PHMSA is revising § 175.10(a)(18) to specify each spare lithium battery must be carried in carry-on baggage only.

Section 175.30 Inspecting Shipments

Section 175.30 establishes requirements for acceptance and carriage of hazardous materials by aircraft. We are adding a new paragraph (a)(5) to this section to specify that the air carrier must not accept a lithium battery shipment described on alternative written documentation unless it is in compliance with § 173.185(c)(4)(v)(B).

Section 175.33 Shipping Paper and Notification of the Pilot-in-Command

Section 175.33 establishes requirements for a shipping paper to accompany an air shipment of hazardous materials and for the aircraft operator to notify the pilot-in-command of the specific information about the hazardous materials to be transported on the aircraft. We are adding a new paragraph (a)(12) to this section to specify that the air carrier must notify the pilot-in-command of the UN number, the hazard class, the number of packages, and the gross mass of every package for each shipment of lithium batteries containing more than 2 small lithium batteries or 8 small lithium cells in any package that otherwise meet the requirements of § 173.185(c). We are also adding a new paragraph (c)(5) to this section to specify that when alternative written documentation is supplied by the shipper in accordance with § 173.185(c)(4)(v)(B), the operator must retain this documentation for 90 days.

Section 175.75 Quantity Limitations and Cargo Location

In § 175.75, the HMR prescribe quantity limits and stowage locations for various hazardous materials aboard an aircraft. In the NPRM, PHMSA proposed to modify § 175.75 to prohibit the stowage of lithium batteries in an inaccessible manner, unless the inaccessible cargo compartment or freight container was equipped with an FAA-approved fire suppression system or the lithium batteries were packaged in an FAA-approved fire resistant container. We also invited comments on whether limiting the number of lithium batteries in a single aircraft, compartment, or unit load device would further enhance safety.

- Stowage Location.

Our proposal to restrict locations for stowage of lithium batteries onboard an aircraft was based on NTSB recommendations A–07–104 and A–07–105 and FAA testing that demonstrated that lithium batteries are a potential fire source and can also enhance the severity of a fire from an outside source.

While the cargo compartments of passenger aircraft are required to be equipped with fire suppression systems, and some cargo-only aircraft are equipped with FAA-approved fire suppression systems, the specific number of such cargo-only aircraft remains unknown. The NTSB stated that it believes this leaves flight crews on cargo-only aircraft at risk from in-flight fires involving both primary and secondary lithium batteries.

PHMSA received many comments on these proposals from a variety of sources including passenger airlines, express air carriers, medical device manufacturers, retailers, airline pilot organizations, the NTSB, members of the U.S. House of Representatives, battery and electronic equipment manufacturers, and others who ship lithium batteries and lithium battery powered equipment. While some welcomed the proposed requirements, most commenters opposed additional loading and segregation requirements. These commenters stated that the proposed additional requirements are unnecessary, and would impose significant cost and logistical hurdles on air carriers resulting in delays, frustrated shipments, and other adverse distributional effects.

The NTSB, ALPA, TDD and IFALPA support additional controls on the stowage of lithium batteries aboard aircraft. These commenters stated that the quantity of lithium batteries in any single location, or in a single cargo compartment, must be restricted to mitigate the consequences of an incident by controlling the number of batteries in close proximity to each other. ALPA stated that it is vitally important to limit the quantity of lithium ion batteries stored in a single location as well as in a single cargo compartment. ALPA supported this statement by saying that, since a fire may be the result of an internal short circuit, defective design, or counterfeit battery, no amount of packaging or training will prevent every incident; however, the severity of an incident may be effectively managed by controlling the number of batteries in close proximity to each other.

ALPA and TDD do not support any proposal that permits the placement of lithium ion batteries in an accessible cargo position as an alternative to stowing the batteries in a Class C cargo compartment. ALPA stated that, if a Class C compartment does not exist on an aircraft, PHMSA should not permit shipments of these batteries on board the aircraft unless additional testing determines that they can be safely transported in a Class E cargo compartment. ALPA and TDD stated

that, if a fire were to occur in an accessible location, it is unlikely that a crewmember would attempt to extinguish the fire using a hand-held halon fire extinguisher.

NTSB noted in its comments that halon fire suppression is ineffective on fires involving lithium metal batteries and suggested that PHMSA could improve the NPRM by explicitly requiring shipments of lithium metal batteries to be loaded in FAA-approved fire resistant containers. Several commenters, including AFA, TIA, AHS, A4A, NAC, and TIACA, questioned the proposal to permit an FAA-approved container for the purposes of transporting lithium batteries. These commenters suggest that unless PHMSA identifies a suitable container or criteria for such a container, this option does not offer any relief.

More commenters opposed additional loading and segregation requirements. These commenters stated that the proposed additional requirements are unnecessary, and would impose significant cost and logistical hurdles on air carriers resulting in delays, frustrated shipments, and other adverse distributional effects. A number of them, including airlines, express air carriers, retailers, medical and other equipment manufacturers, expressed concerns about the impact of stowage restrictions on aircraft cargo capacity. Saft and IATA stated that, unlike passenger-carrying aircraft, many existing cargo aircraft do not have, and are not required to be fitted with, Class C cargo compartments. Therefore, if the stowage requirements outlined in the NPRM were finalized, such cargo-only aircraft could only carry lithium batteries in an accessible location. FedEx and others stated that a requirement for lithium ion batteries to be accessible would place them together with other highly regulated and flammable substances, increasing the potential for igniting or increasing the severity of an onboard fire. Similarly, UPS stated that the proposed stowage requirements would have the practical effect of making crew accessible positions the most common method of handling lithium batteries and devices shipped with them. Currently, very few positions on UPS aircraft are accessible, and typically UPS reserves such positions for high-hazard materials currently subject to accessibility requirements. UPS further stated that such consolidation may present commercial issues to air carriers whose customers may, for sanitation and other reasons, seek to forbid locating their lithium battery-powered products near traditional cargo aircraft-only

shipments. These commenters stated that such restrictions will likely result in aircraft operators electing to simply ban the transport of such materials or load these products on passenger-carrying aircraft rather than run the risk of non-compliance with the HMR.

Digital Europe asked PHMSA to consider that only bulk shipments of lithium batteries should potentially require additional stowage and segregation. It asserts that, by volume, lithium batteries contained in equipment will put the most demand on crew accessible stowage. Casio stated that lithium ion batteries packed with, or contained in, products constitute a small volume of the overall package and a restriction that includes batteries packed with or contained within products may have a significant impact on the availability of cargo space. NetApp illustrated this fact with their experience shipping large equipment that also contains several small lithium batteries.

CIPA and Olympus stated that if one cell or battery causes a fire within a package complying with the ICAO Technical Instructions, the fire will self-terminate without spreading to other batteries or the contents of the same package. Accordingly, there is no need for additional restrictions. Air carriers, including UPS, FedEx, Delta and Southwest, stated that the proposed restrictions would further complicate the loading process and require an overhaul of training and operational procedures. Delta and others commented that the HMR currently impose compartment limits at the hazard class or division level, but not to specific UN numbers. They stated that, since the HMR do not impose loading restrictions on Class 9 material, PHMSA must establish loading limits for lithium batteries specific to those UN numbers. Subsequently, each carrier would then be required to develop a process to ensure compliance with this regulation. These commenters stated that managing such accessibility limitations at the UN number level would impose great difficulties on air carriers.

UPS stated that its loaders would be required to scrutinize the UN number and proper shipping names marked on all Class 9 shipments in order to identify those packages subject to new accessibility requirements. In addition, UPS stated that it will need to reprogram electronic systems developed to support the loading of aircraft unit load devices (ULDs) and aircraft, as well as generate a notice to the pilot, specifically to address the lithium battery specific requirements. Alaska Airlines, Horizon Air, and NAC

proposed creating an additional hazard class for lithium batteries if loading limits are needed, thereby reducing the complications associated with segregating packages based on the UN number. While a separate hazard class for lithium batteries would assist in identification, and subsequent segregation, of such packages for transport, PHMSA does not believe creating a new hazard class for a single commodity is appropriate.

VFS stated that it is developing a ULD that has a means to alert a pilot or flight crewmember of the presence of smoke and control or extinguish a fire inside of a ULD without requiring a crewmember to enter the compartment. PHMSA and FAA applaud these efforts and welcome such innovations.

- **Quantity Limits.**

In response to PHMSA's invitation for comments on limiting the number of lithium batteries in a single aircraft, compartment, ULD, pallet, or similar overpack, IATA and TTI stated that the guiding principle established in the ICAO Technical Instructions is that packaging requirements and the package limits for hazardous materials reduce the hazard in air transport to an acceptable level. On that basis, there is no limit on the number of individual packages of hazardous materials that may be transported in a single aircraft, single cargo compartment, or ULD unless there is a need to separate or segregate packages containing incompatible hazardous materials.

PRBA stated that there is no reasonable basis to limit the number of lithium ion or metal battery packages in a single aircraft cargo compartment, ULD, or overpack. PRBA expanded on this by stating that the HMR already contain: (1) Strict weight restrictions on these packages; (2) quantity limits for batteries packed with, or contained in, equipment; and (3) a prohibition against shipping lithium metal batteries on passenger-carrying aircraft. These restrictions adequately address what PRBA understands to be PHMSA's justification for this proposal, i.e., to mitigate the consequences of a fire involving lithium ion and lithium metal batteries. NEMA echoed these statements by commenting that, if a package is properly packaged and labeled in compliance with the current regulations, it should be allowed to ship without any further restrictions. Delta questioned the basis upon which PHMSA and FAA would formulate a compartment limit.

PHMSA and FAA continue to study these issues and will take into consideration new suppression systems and agents as they become available in

the future. We are not adopting stowage restrictions or limits on the number of for lithium batteries in a single aircraft, aircraft compartment, ULD, pallet or overpack.

E. Compliance Date

PHMSA's January 11, 2010, NPRM proposed a 75-day period for affected entities to come into compliance with the provisions of the NPRM. ALPA favored expedited compliance with the safety regulations, stating that the provisions, once enacted, would have a significant positive impact on safety and may preclude the need to prohibit the transport of lithium batteries aboard aircraft. However, nearly all other commenters opposed the 75-day period for compliance with the requirements outlined in the NPRM. These commenters stated that a 12–18 month compliance period would be required if PHMSA adopted the provisions of the NPRM. The commenters noted various barriers to immediate compliance including training hazmat employees, certifying packaging, obtaining various approvals, and modifying their logistical operations.

The provisions of this final rule harmonize the HMR with the UN Model Regulations, the ICAO Technical Instructions, and the IMDG Code, so we do not anticipate significant barriers to compliance. In the April 2012 notice, we requested comments on ways to reduce the compliance burden should PHMSA adopt in a final rule the ICAO revisions. Outside of a delayed effective date, commenters did not provide any comment on ways that PHMSA could reduce the burden or costs of implementation of a final rule. Most commenters supported a January 1, 2013, effective date since the 2013–2014 ICAO Technical Instructions also become effective on January 1, 2013. Commenters suggested that PHMSA provide a suitable grace period to allow shipments that were initiated prior to January 1st to reach their destination. Others suggest longer grace periods between one month and 18 months. The delayed effective date would permit the incorporation of new requirements into standard operating procedures and for the training of affected personnel.

In order to facilitate harmonization, and permit the acceptance of lithium battery shipments made in accordance with the 2013–2014 ICAO Technical Instructions, PHMSA permits immediate voluntary compliance with all of the provisions in this final rule. PHMSA will not require compliance with the requirements of this final rule until six months after publication in the **Federal Register**.

IV. Regulatory Analyses and Notices

A. Statutory/Legal Authority for This Rulemaking

This final rule is published under the following statutory authorities:

1. 49 U.S.C. 5103(b) authorizes the Secretary of Transportation to prescribe regulations for the safe transportation, including security, of hazardous material in intrastate, interstate, and foreign commerce.

2. 49 U.S.C. 44701 authorizes the Administrator of the Federal Aviation Administration to promote the safe flight of civil aircraft in air commerce by prescribing regulations and minimum standards for practices, methods, and procedures that the Administrator finds necessary for safety in air commerce and national security. Under 49 U.S.C. 40113, the Secretary of Transportation has the same authority to regulate the transportation of hazardous materials by air, in carrying out § 44701, that he has under 49 U.S.C. 5103.

3. 49 U.S.C. 5120(b) authorizes the Secretary of Transportation to ensure that, to the extent practicable, regulations governing the transportation of hazardous materials in commerce are consistent with standards adopted by international authorities. This rule amends the HMR to maintain alignment with international regulatory approaches by incorporating various amendments to facilitate the transport of hazardous material in international commerce. To this end, as discussed in detail above, the rule incorporates changes into the HMR found in the 5th revised edition of the UN Manual of Tests and Criteria, the seventeenth revised edition of the UN Recommendations, Amendment 36–12 to the IMDG Code, and the 2013–2014 ICAO Technical Instructions, which became effective January 1, 2013.

4. Section 828 “FAA Modernization and Reform Act” (Pub. L. 112–95; 126 Stat. 133 (Feb 14, 2012)) prohibits DOT agencies from issuing or enforcing regulations regarding the air transport of lithium cells or batteries, whether transported separately or packed with, or contained in, equipment, if the requirement is more stringent than the requirements of the ICAO Technical Instructions. However, the legislation authorizes the continued prohibition on the transport of lithium metal cells and batteries aboard passenger aircraft and authorizes the issuance of more stringent regulation based on credible reports that lithium batteries substantially contributed to the initiation or propagation of a fire aboard an aircraft. Such regulations must address solely the deficiencies

referenced in the report and must be the least disruptive and least expensive variation from existing requirements while adequately addressing identified deficiencies.

B. Executive Order 12866, Executive Order 13563, and DOT Regulatory Policies and Procedures

This final rule is considered a significant regulatory action under Executive Order 12866 and the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034) because of significant public interest. A regulatory impact assessment is available for review in the public docket for this rulemaking.

Executive Orders 12866 and 13563 require agencies to regulate in the “most cost-effective manner,” to make a “reasoned determination that the benefits of the intended regulation justify its costs,” and to develop regulations that “impose the least burden on society.” In this final rule, PHMSA is amending the HMR to harmonize requirements for the transport of lithium batteries with requirements in the UN Model Regulations, 2013–2014 ICAO Technical Instructions, and the IMDG Code by: (1) Adopting separate shipping names for (i) lithium metal batteries, lithium metal batteries contained in equipment, and lithium metal batteries packed with equipment; and (ii) lithium ion batteries, lithium ion batteries contained in equipment, and lithium ion batteries packed with equipment; (2) adopting “Watt-hours” as the measure of the size of a lithium ion battery to replace the current use of “equivalent lithium

content;” (3) revising various definitions consistent with the UN Model Regulations; (4) adopting into the HMR the ICAO exception for packages containing up to 2 small lithium batteries or 8 small lithium cells; (5) for lithium ion batteries that meet the conditions in the exception, requiring each package to bear a lithium battery handling label; and (6) revising package weight limits applicable to different lithium battery types and configurations.⁷ PHMSA is retaining its prohibition on the transport of lithium metal batteries aboard passenger aircraft. PHMSA considered three potential regulatory options.

- Option 1 is a no-action option. This would retain the current provisions applicable to lithium batteries. All costs and benefits are relative to this option.
- Option 2 would amend the HMR applicable to the transport of lithium cells and batteries consistent with the UN Model Regulations, the ICAO Technical Instructions and the IMDG Code. This option would provide an exception for shipments of a limited number of small lithium batteries and battery powered equipment, but retains the current prohibition on the transport of lithium metal batteries aboard passenger aircraft.
- Option 3 would eliminate the regulatory exceptions for small lithium batteries—including batteries packed with, or contained in, equipment—and require their shipment as fully regulated Class 9 materials. This option would additionally (1) modify the design change criteria in the UN Manual of Tests and Criteria; (2) require lithium cells and batteries to be marked with an

indication that the cell or battery design that passed each of the appropriate tests outlined in the UN Manual of Tests and Criteria and (3) limit the locations on board aircraft where shipments of lithium cells and batteries could be stowed.

PHMSA has chosen the Option 2—harmonization with UN Model Regulations, the ICAO Technical Instructions and the IMDG Code. This option was constructed with the input of stakeholders representing the aviation, manufacturing, and shipping industries, as well as international governments and safety agencies. It is the result of compromise directed at producing a strong yet flexible regulation and reflects Congressional intent and stakeholders’ need for a global standard.

To evaluate the impact of the rule, PHMSA used market research and information provided by commenters to the April 11, 2012, notice to project the total numbers of packages and shipments that the regulation would affect. PHMSA first quantified the number of lithium batteries transported to or from the U.S., and then estimated the number of shipments potentially affected by this rule. Trade data from 2011 were inflated assuming a constant 10% growth rate, with an expected 2.8 billion batteries, packed in nearly 1.1 million shipments, moving to or through the U.S. for the decade spanning 2014 to 2023. The following table shows the 10-year projected number of lithium battery shipments potentially affected by this rule.

	2014–2023	Batteries (millions)	Shipments
Imports		2,836.1	710,626
Domestic origin		2.6	436,814
Total		2,838.8	1,147,440

Lithium batteries imported into the U.S. over the next 10 years are considered to be consolidated into shipments holding an average of 4,000 batteries each (based on historical data), whereas anecdotal evidence from commenters engaged in domestic custom battery production indicated that their shipments were mostly small runs of specialized batteries, with an average of a half dozen batteries per package.

Due to uncertainty inherent in much of the data collected for this analysis, we have used a probabilistic method observing the overall distribution of possible costs to observe the range of potential outcomes resulting from adoption of the provisions in the final rule. Figures listed here are mean (average) costs.

Costs resulting from the regulatory changes are the sum of: Hazard communication costs, including labeling, documentation, and package

inspection; training and employment costs; and cost associated with the generation and retention cell/battery design testing records information. Hazard communication broadly refers to package markings, labels, documentation, and acceptance checks. The hazard communication cost increases, as a result of adopting the provisions of the new rule, would be calculated by multiplying the number of shipments required to comply with enhanced hazard communication

⁷ In this document, “configurations” refers to the relevance of differences between batteries-only

shipments, batteries packed with equipment, and batteries contained in equipment.

requirements by the increased cost per shipment. Training costs would be limited to a one-time expenditure by shippers to familiarize staff with the new regulations, while carriers would be presumed to undergo supplemental training on the revised ICAO Technical Instructions, regardless of U.S. action in a final rule. Cost associated with battery design testing would be a nominal sum resulting from the generation of battery design testing records. Using both 3% and 7% annual discounting for future costs, the total present value mean cost of the regulation from 2014 to 2023 is expected to be between \$10.1 million (at 7% discount) and \$11.2 million (at 3% annual discount), with a possible range of \$6.9 million to \$15.3 million in 2013 dollars.

Benefits for this rulemaking are based on the potential to avert consequences from catastrophic incidents that would otherwise occur without the provisions of the rule. However, due to the inherent uncertainty of potential and averted consequences, quantification of the benefits is so imprecise that PHMSA elected not to estimate them. PHMSA has instead elected to engage in a break-even analysis to determine the threshold safety benefit that would make this rule cost beneficial. This estimation still requires PHMSA to estimate the expected cost of aircraft incidents involving lithium batteries.

PHMSA weighs the relative probabilities of an incident occurring on a cargo-only aircraft and a passenger aircraft by assuming on average an 80%

chance of an incident occurring onboard a cargo-only and 20% chance on a passenger flight. This roughly matches the proportion of total cargo that is carried on cargo-only aircraft and passenger aircraft. The average expected incident has costs of \$354 million, which is \$302 million when discounted at 3 percent, and \$279 million when discounted at 7 percent.

Table 3–2–3 presents the number of incidents that would need to be prevented in order for this rule to be cost-beneficial. For instance, using the base case for costs, this rule would need to prevent more than 0.041 incidents over the next 10 years, discounted at 3 percent, for the benefits to exceed the costs.

TABLE 3–2–3—BREAK-EVEN POINTS, NUMBER OF INCIDENTS PREVENTED

	Discounted 3%	Discounted 7%
Low cost estimate	0.029	0.03
Base case cost estimate	0.041	0.043
High case cost estimate	0.056	0.061

C. Executive Order 13132

The requirements in this rule will preempt state, local, and Indian tribe requirements but do not have substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

The Federal hazardous materials transportation law, 49 U.S.C. 5101 et seq., contains an express preemption provision (49 U.S.C. 5125(b)) preempting State, local, and Indian tribe requirements on the following subjects:

- (1) The designation, description, and classification of hazardous materials;
- (2) The packing, repacking, handling, labeling, marking, and placarding of hazardous materials;
- (3) The preparation, execution, and use of shipping documents related to hazardous materials and requirements related to the number, contents, and placement of those documents;
- (4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; or
- (5) The design, manufacture, fabrication, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified

for use in transporting hazardous material.

Federal hazardous materials transportation law provides at 49 U.S.C. 5125(b)(2) that, if DOT issues a regulation concerning any of these subjects, DOT must determine and publish in the **Federal Register** the effective date of Federal preemption. The effective date may not be earlier than the 90th day following the date of issuance of the final rule and not later than two years after the date of issuance.

This final rule addresses subject items (1), (2), (3), and (4) above and preempts State, local, and Indian tribe requirements not meeting the “substantively the same” standard. The effective date of Federal Preemption is November 4, 2014.

D. Executive Order 13175

This final rule was analyzed in accordance with the principles and criteria contained in Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. Because this final rule does not have tribal implications and does not impose substantial direct compliance costs, the funding and consultation requirements of Executive Order 13175 do not apply.

E. Regulatory Flexibility Act, Executive Order 13272, and DOT Procedures and Policies

This final rule has been developed in accordance with Executive Order 13272,

Proper Consideration of Small Entities in Agency Rulemaking, and DOT’s procedures and policies to promote compliance with the Regulatory Flexibility Act (Pub. L. 96–354) and to ensure potential impacts of rules on small entities are properly considered. The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to review regulations to assess their impact on small entities, unless the agency determines that a rule is not expected to have a significant impact on a substantial number of small entities.

1. Need for and Objectives of the Rule

The intent of this action is to align the HMR with international transport standards and requirements to the extent practicable in accordance with Federal Hazardous Materials transportation law (see 49 U.S.C. 5120). Our goal is to harmonize, without diminishing the level of safety currently provided by the HMR, and not impose undue burdens on the regulated public. This action is necessary to incorporate changes adopted in the UN Recommendations on the Transport of Dangerous Goods—Model Regulations, the ICAO’s Technical Instructions for the Safe Transport of Dangerous Goods by Air, and the IMDG Code, effective January 1, 2013.

2. Comments to the Initial Regulatory Flexibility Analysis

PHMSA received comments on the initial regulatory flexibility analysis from industry trade associations and SBA. Small businesses including Fedco and ICCNexergy added figures detailing their expected burden.

SBA and PRBA stated that the proposed rules would create conflicting standards and require significant supply chain redesigns. Further, SBA stated that the initial regulatory flexibility analysis understated the number of, and impact on, small businesses that support the retail sector, including internet shippers, manufacturers of battery packs, shipping companies, and airlines that handle lithium batteries or electronic devices containing lithium batteries. SBA recommended that PHMSA conduct further outreach to the regulated community to enhance dialogue, promote safety and ensure harmonization.

We have been attentive to the concerns of small businesses through the preparation of the rule and its supporting analyses. Data provided by several commenters suggested that a significant percentage of lithium batteries transported in the U.S. affected by this rule are packed with, or contained in, equipment and often those pieces of equipment only contain one device per package. When developing the rule, PHMSA examined alternatives for reducing the regulatory compliance burden on small entities, including providing exceptions for certain finished medical devices and extending the compliance date to permit extra time for small entities to come into compliance. In this final rule, we are maintaining existing exceptions:

- For the transport of lithium batteries by modes other than aircraft (i.e. highway, rail and vessel), including batteries packed with, or contained in, equipment; and
- for the air transport of packages containing up to 8 small lithium cells or 2 small lithium batteries and lithium batteries packed with, or contained in, equipment.

3. Description and Estimate of the Number of Small Entities to Which the Final Rule Will Apply

Two types of small businesses are likely to incur costs associated with compliance with the provisions of this rule—(1) manufacturers and distributors of lithium batteries and (2) air carriers. We employ the thresholds published by the Small Business Administration for industries subject to the HMR—generally, this includes those that have

up to 500 employees. Our research has identified 130 possible entities: 60 manufacturers and sellers, and 70 air transporters.

PHMSA reviewed records of the potentially affected small manufacturing and sales businesses by NAICS codes—discussed in greater detail in the Regulatory Flexibility Analysis—and determined that of the 60 identified:

- 29 are classified as manufacturers of primary or storage batteries;
- 16 are classified as manufacturers of equipment, other devices, or components of these articles;
- 13 are classified as wholesalers of equipment or parts; and
- 2 are engaged in research and development.

Through the preparation of this analysis, there has been no evidence of retailers other than the manufacturers and wholesalers above that specialize in lithium battery sales.

PHMSA then identified air transportation businesses by NAICS code, and found that there are 642 businesses with fewer than 1,000 employees offering either scheduled air transportation (passenger or freight only) or chartered freight transportation. Of these, 572 had 100 or fewer employees and were judged to be unlikely to carry enough cargo that the impact of the revised regulation would be considered significant. Thus there are 70 air carriers potentially affected.

4. Description of the Projected Reporting, Record Keeping and Other Compliance Requirements for Small Entities

The costs accruing to small businesses are not anticipated to be significant.

- Hazard communication: The adoption of the 2013–2014 ICAO Technical Instructions for the majority of projected shipments is unlikely to generate substantial new costs. The total estimated cost for the entire industry over the next decade is between \$1.5 and \$2.1 million; the proportion applicable to small businesses is negligible.

- Training: PHMSA estimates that a company will spend between \$300 and \$400 to train an employee once, with subsequent trainings being required independent of this regulation. While this figure represents the largest individual cost under consideration in this analysis, the small businesses that commented on the Initial Regulatory Flexibility Analysis (IRFA) state that they do currently package fully regulated Class 9 shipments, indicating that these costs are at least already partly borne by such businesses.

- Records of Design Testing: The final rule requires the development and retention of battery-design testing results. The projected cost of these activities is estimated at \$110,000 over the next 10 years; the proportion applicable to small businesses is negligible.

5. Steps PHMSA Has Taken To Minimize the Significant Economic Impact on Small Entities

There are no alternatives to the final rule that would accomplish the stated objectives of the rule, which are to reduce the risk posed by the transport of lithium batteries and to harmonize the domestic HMR with international rules. As discussed in IV. B. of the preamble to this final rule, PHMSA considered a number of regulatory options: (1) A do nothing option, (2) an option that would harmonize the HMR with the requirements of the UN Model Regulations, the ICAO Technical Instructions and the IMDG Code, and (3) an option consistent with eliminating regulatory exceptions for the transport of small lithium cells and batteries. PHMSA chose the second option because it was constructed with the input of stakeholders representing the aviation, manufacturing, and shipping industries, international governments, and safety agencies. It is the result of compromise directed at producing a strong yet flexible regulation and reflects congressional intent and stakeholders' need for a global standard. Harmonizing the domestic HMR with the requirements of the UN Model Regulations, the ICAO Technical Instructions and the IMDG Code provides the most flexibility while increasing safety levels. Based on this analysis, we certify that this final rule does not impose a significant economic impact on a substantial number of small entities.

F. Paperwork Reduction Act

PHMSA currently has approved information collections under Office of Management and Budget (OMB) Control Number 2137–0034, “Hazardous Materials Shipping Papers and Emergency Response Information” which is currently under OMB review and OMB Control Number 2137–0572, “Testing Requirements for Non-Bulk Packaging,” with an expiration date of July 31, 2015. This final rule will result in an increase in the annual burden of these information collections due to amendments being adopted in this final rule. IATA states that, based on calculations for the completion of a shipping paper for various types of shipments of lithium batteries, it takes

between 3 minutes and 10 minutes to produce a shipping paper and additional time associated with collection of data to complete the information required on the written information to the pilot-in-command (NOPIC) as required by § 175.33 of the HMR. IATA also states that PHMSA's estimate of consolidated shipments to be inaccurate. The commenter states that while there is some level of package consolidation for shipments of batteries and for equipment shipped with batteries from the point of manufacture to a distribution center, the same is not necessarily true for shipments from a distribution center.

PHMSA has re-evaluated the additional time for a transport worker to review and complete an existing shipping document; PHMSA's revised estimate accounts for the reduced regulatory burden of this final rule relative to the NPRM and the revised estimate also accounts for the additional time required by shippers of batteries and assumes lithium battery shippers often repeatedly offer the same hazardous materials and have developed the ability to automate many administrative processes. PHMSA has adjusted the paperwork burden imposed by the requirements of this final rule accordingly.

Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it is approved by OMB and displays a valid OMB control number. Section 1320.8(d), Title 5, Code of Federal Regulations requires that PHMSA provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests.

OMB Control No. 2137-0034

Hazardous Materials Shipping Papers and Emergency Response Information

Additional Annual Number of Respondents: 670.

Additional Annual Number of Responses: 143,430.

Additional Annual Burden Hours: 2,390.

Additional Annual Burden Costs: \$47,800.

OMB Control No. 2137-0572.

Testing Requirements for Non-Bulk Packaging

Additional Annual Number of Respondents: 110.

Additional Annual Number of Responses: 1,100.

Additional Annual Burden Hours: 550.

Additional Annual Burden Costs: \$11,000.

Requests for a copy of this information collection should be directed to: Steven Andrews or T. Glenn Foster, Office of Hazardous Materials Standards (PHH-10), Pipeline and Hazardous Materials Safety Administration, Room E24-426, 1200 New Jersey Ave. SE., Washington, DC 20590-0001, telephone (202) 366-8553.

G. Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center generally publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

H. Unfunded Mandates Reform Act

This final rule does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995. It does not result in costs of \$140,800,000 or more, adjusted for inflation, to either State, local or tribal governments, in the aggregate, or to the private sector in any one year, and is the least burdensome alternative that achieves the objective of the rule.

I. Environmental Assessment and Finding of No Significant Impact

The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4347) requires Federal agencies to consider the environmental impacts of major Federal actions and prepare a detailed statement for actions significantly affecting the quality of the human environment. For those actions that are unlikely to have significant environmental impacts, the Council on Environmental Quality (CEQ) regulations (40 CFR parts 1500-1508) require Federal agencies to conduct an environmental assessment that includes (1) the need for the action, (2) alternatives to the action, (3) probable environmental impacts of the action and alternatives, and (4) the agencies and persons consulted during the consideration process (40 CFR 1508.9).

1. Purpose and Need

This final rule amends the requirements for the transport of lithium batteries. Most of these amendments harmonize the HMR with its international equivalents and focus on packaging, hazard communication and training. These measures serve to ensure that lithium batteries are safe for transport and the hazards associated with lithium batteries are properly communicated. Thus, most of the

amendments of this final rule have no environmental impact. However, we are amending the requirements applicable to the transport of transport of lithium batteries for disposal or recycling. This section focuses on the environmental impacts of these activities under each of the alternatives considered.

Once lithium batteries reach the end of their useful life they must be recycled or properly disposed. The environmental benefits and policy need for battery recycling have been demonstrated through the enactment of battery recycling laws by more than half the states and Puerto Rico. Several states have also enacted laws specifically mandating the recycling of lithium ion batteries.⁸ Appropriate transport safety regulations will ensure that lithium batteries can be safely and efficiently transported for disposal or recycling. Any provisions for the transport of lithium batteries must balance the need to facilitate transport with the need to ensure that the hazards posed by lithium batteries in transport are appropriately managed.

2. Alternatives

In developing this rule, PHMSA considered three regulatory options: (1) A do nothing option (no action alternative); (2) an option that would expand the current recycling and disposal provisions thus facilitating more movement; and (3) an option that eliminates regulatory exceptions for the transport of small lithium cells and batteries. This would require lithium batteries shipped for disposal or recycling to meet all of the requirements applicable to new batteries.

The second option is the selected alternative. PHMSA has chosen this alternative because it was constructed with the input of stakeholders representing the, manufacturing, and shipping industries, environmental concerns and battery recyclers. This option requires lithium batteries to be packaged to reduce the possibility of damage that could lead to an incident; and accompanied by hazard information that ensures appropriate and careful handling and informs transport workers and emergency response personnel of actions to be taken in an emergency.

The do nothing option does not achieve the stated objective of ensuring the safe transport of lithium batteries for disposal or recycling.

The third option was judged too costly and onerous to industry relative

⁸ Source: Call2Recycle, Inc a battery product stewardship program; <http://www.call2recycle.org/recycling-law-map/>.

to potential benefits, and was thus eliminated.

3. Analysis of Environmental Impacts

Hazardous materials are substances that may pose a threat to public safety or the environment during transportation because of their physical, chemical, or nuclear properties. The hazardous material regulatory system is a risk management system that is prevention-oriented and focused on identifying a safety hazard and reducing the probability and quantity of a hazardous material release. The regulations require each shipper to classify a material in accordance with these hazard classes; the process of classifying a hazardous material is itself a form of hazard analysis. Further, the regulations require the shipper to communicate the material's hazards through use of the hazard class, and proper shipping name on the shipping paper and the use of labels on packages and placards on transport vehicles. Thus, the shipping paper, labels, and placards communicate the most significant findings of the shipper's hazard analysis. Hazardous materials are often further sub-categorized to one of three packing groups based upon its degree of hazard—from high-hazard Packing Group I to a low-hazard Packing Group III material. The quality, damage resistance, and performance standards of the packaging in each packing group are appropriate for the hazards of the material transported.

Releases of hazardous materials, whether caused by accident or deliberate sabotage, can result in explosions or fires. Radioactive, toxic, infectious, or corrosive hazardous materials can have short-term or long-term exposure effects on humans or the environment. Generally, however, the hazard class definitions are focused on the potential safety hazards associated with a given material, or type of material, rather than the environmental hazards of such materials.

Lithium is the lightest solid metal. It can be absorbed into the body by inhalation of its aerosol and by ingestion and is corrosive to the eyes, the skin, and the respiratory tract. Lithium reacts violently with strong oxidants, acids, and many compounds (hydrocarbons, halogens, halons, concrete, sand and asbestos) causing a fire and explosion hazard. In addition, lithium reacts with water, forming highly flammable hydrogen gas and corrosive fumes of lithium hydroxide. Lithium hydroxide represents a potentially significant environmental hazard, particularly to water organisms.

Lithium metal batteries contain no toxic metals.

Lithium ion batteries contain an ionic form of lithium but no lithium metal. Lithium ion batteries do not pose an environmental hazard and are safe for disposal in the normal municipal waste stream. While other types of batteries include toxic metals such as cadmium, the metals in lithium ion batteries—cobalt, copper, nickel and iron are considered safe for landfills or incinerators. The primary hazard posed by lithium batteries are their ability to overheat and ignite, and once ignited, the resulting fires can be especially difficult to extinguish. The likelihood to overheat or ignite is increased if the batteries are poorly packaged, damaged or exposed to a fire or a heat source. When packaged and handled properly, lithium batteries pose no environmental hazard.

While the HMR contain provisions applicable to the transport of lithium batteries for disposal or recycling several commenters expressed concern about a do nothing option. GRC stated that the current provisions do not exclude the responsibility for hazardous materials training for their suppliers and that training in accordance with part 172, subpart H would be virtually impossible, given the nature of their participating organizations and the number of collection sites that include non-profits, schools, retailers, community groups, and businesses. CEA contended that a do nothing option will ultimately act as a disincentive for consumers to recycle responsibly. PHMSA agrees with CEA's comment that the do nothing alternative would reduce battery recycling compared with the preferred alternative.

We also considered an option that would impose additional safety requirements on the transport of lithium batteries for disposal or recycling, including a requirement that such batteries be placed in specification packages. We considered this option because lithium batteries of all sizes can be transported for disposal or recycling and the batteries are often from an uncertain origin, may be damaged and there is no guarantee that the batteries have a low energy level. Enhanced safety requirements may be appropriate in some cases. This option was ultimately rejected because this would not facilitate battery recycling and would generate only marginal additional safety benefits and potentially result in additional environmental impacts from the use of additional packaging.

RBRC stated that, for this rule to be successful there must be a specific

provision dealing with collection for recycling programs that recognizes the simple fact that most used batteries collected are, by their very nature, in a low state of charge. With this in mind, we developed measures to expand the current lithium battery recycling provisions with the aim to facilitate the transport of most lithium batteries i.e. those used in consumer electronic devices consistent with current exceptions for the transport of small lithium cells and batteries. PHMSA ultimately selected this option because it was determined to pose little adverse impact to the environment, encourages responsible end of life practices for lithium batteries and provides a means to safely transport lithium batteries for their final disposition. The measures in this option reduce the risks to people and the environment posed during transportation of lithium metal and lithium ion batteries by ensuring that the batteries: Withstand conditions normally encountered in transportation, are packaged to reduce the possibility of damage that could lead to an incident, and minimize the consequences of an incident. Additionally, the provisions of this option facilitate the collection and safe transport of used lithium cells and batteries for recycling or disposal.

4. Consultation and Public Comment

PHMSA received numerous comments to the NPRM (75 FR 1302, Jan. 11, 2010) and the April 11, 2012 (77 FR 21714) **Federal Register** notice that sought further comments on the impacts of revisions to the HMR applicable to lithium batteries. The commenters who responded to the draft environmental impact statement included Black and Decker, the Environmental Technology Council, UTC, CERC, ITI, PRBA, the Lithium Battery Industry Coalition, GRC, and CEA. These commenters supported provisions for the transport of lithium batteries for recycling. They stressed the need to maintain exceptions for the transport of small (consumer type) lithium batteries. ITI stated that the initial environmental impact statement published in the NPRM lacks an analysis of the impact that classifying consumer electronic equipment as a Class 9 hazardous material would have on waste streams. The commenter stated that such classification would result in significant escalation in the cost of shipping devices containing lithium batteries for proper disposal or recycling. The provisions of this final rule maintain the current exceptions for the transport lithium batteries contained in equipment; thus this final rule will not impact consumer electronic equipment. The Environmental

Technology Council agreed that, while the performance standard may be sufficient for lithium ion batteries, such as those found in cellular phones and notebook computers, this standard may not be appropriate for reactive batteries that pose the greatest risk. The commenter recommended specific measures that should be taken to ensure the safe transport of reactive batteries, including ensuring that batteries are not connected in series, insulating all batteries from each other, and limiting the types and sizes of packagings. The HMR require that lithium batteries be protected from short circuits and damage, as well as separated from each other and other conductive materials. We encourage all shippers and carriers to implement appropriate risk reduction measures commensurate with the hazard posed by an individual shipment. These measures outlined in the HMR are intended to provide flexible, performance-oriented provisions.

5. Finding of No Significant Impact

PHMSA finds that the selected alternative will not have a significant impact on the human environment. Lithium batteries are a key part of strategies to develop greener technologies to power many different applications from automobiles to cellular phones to computers. The measures outlined in this final rule facilitate the safe and efficient transportation of lithium metal and lithium ion batteries across national boundaries from initial manufacture until their eventual disposal or recycling. This regulation is anticipated to result in slight positive impacts on the environment because the regulation provides clear and consistent regulations that reduce the likelihood of a transportation incident involving lithium batteries which would likely cause other secondary environmental impacts. The provisions of this final rule also continue to permit the operation of battery recycling programs throughout the United States.

J. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy. DOT will read and respond to all substantive comments on a rulemaking. If you are filing comments on behalf of an organization or group of individuals, we encourage you to include the name

of your group or organization. However, all comments, even anonymous comments filed on behalf of a group, will be considered if they are timely filed. Including your name/group along with your comment is completely optional.

K. Executive Order 13609 and International Trade Analysis

Under E.O. 13609, agencies must consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are, or would be, adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979 (Pub. L. 96-39), as amended by the Uruguay Round Agreements Act (Pub. L. 103-465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

The Republic of Korea Ministry of Foreign Affairs and Trade, PRBA, NEMA, NAM, Digital Europe, Japan, and the European Union stated that the January 2010 NPRM is inconsistent with the ICAO Technical Instructions. The commenters stated that the proposed elimination of the exceptions for certain lithium batteries when transported by aircraft, and the proposed revision of the design change criteria, would result in an unnecessary increase in transportation, packing, and testing costs for the manufacturers and traders of lithium batteries. These commenters further stated that technical rules and regulations should not be more trade-restrictive than necessary, as stipulated in the relevant World Trade Organization Agreements addressing Technical Barriers to Trade.

PHMSA participates in the establishment of international standards in order to protect the safety of the American public, and we have assessed the effects of this final rule to ensure that it does not cause unnecessary obstacles to foreign trade. This final rule harmonizes the domestic HMR with approaches outlined in the UN Model Regulations, the ICAO Technical Instructions and the IMDG Code. Commenters identified several benefits to adopting the international transport standards for lithium batteries into the domestic regulations, including streamlined shipping practices that reduce cost, a reduction in the potential for confusion and improved shipment safety through increased visibility of lithium battery shipments. Conversely, commenters noted several disadvantages to not adopting the international transport standards into the domestic regulations. The current ICAO Technical Instructions are at least as safety as the current HMR and many commenters stated that the current domestic regulations do not provide the level of safety as the ICAO Technical Instructions. Further, maintaining a dual system hinders consistent enforcement of the requirements and increases the likelihood of frustrated shipments.

The decision to adopt the requirements of the ICAO Technical Instructions into the domestic HMR was guided by the input of stakeholders representing the aviation, manufacturing, and shipping industries, as well as international governments and safety agencies. It is the result of considerations directed at producing a strong yet flexible regulation and reflects Congressional intent and stakeholders' need for a global standard. Accordingly, this rulemaking is consistent with E.O. 13609 and PHMSA's obligations under the Trade Agreement Act, as amended.

List of Subjects

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, Reporting and recordkeeping requirements.

49 CFR Part 172

Education, Hazardous materials transportation, Hazardous waste, Incorporation by reference, Labeling, Markings, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Incorporation by reference, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements, Uranium.

49 CFR Part 175

Air carriers, Hazardous materials transportation, Radioactive materials, Reporting and recordkeeping requirements.

In consideration of the foregoing, we amend 49 CFR Chapter I as follows:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

■ 1. The authority citation for part 171 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.97; Pub. L. 101–410 section 4 (28 U.S.C. 2641 note); Pub. L. 104–134, section 31001.

■ 2. In § 171.8:

■ a. The definitions for “Aggregate lithium content” and “Equivalent lithium content” and “Lithium content” are removed.

■ b. The definitions for “Lithium ion cell or battery” “Lithium metal cell or battery”, “Short circuit” and “Watt-hour” are added in alphabetical order.

The additions read as follows:

§ 171.8 Definitions and abbreviations.

* * * * *

Lithium ion cell or battery means a rechargeable electrochemical cell or battery in which the positive and negative electrodes are both lithium compounds constructed with no metallic lithium in either electrode. A lithium ion polymer cell or battery that uses lithium ion chemistries, as described herein, is regulated as a lithium ion cell or battery.

Lithium metal cell or battery means an electrochemical cell or battery utilizing lithium metal or lithium alloys as the anode. The lithium content of a lithium metal or lithium alloy cell or battery is measured when the cell or battery is in an undischarged state. The lithium content of a lithium metal or lithium alloy battery is the sum of the grams of lithium content contained in the component cells of the battery.

* * * * *

Short circuit means a direct connection between positive and

negative terminals of a cell or battery that provides an abnormally low resistance path for current flow.

* * * * *

Watt-hour (Wh) means a unit of energy equivalent to one watt (1 W) of work acting for one hour (1 h) of time. The Watt-hour rating of a lithium ion cell or battery is determined by multiplying the rated capacity of a cell or battery in ampere-hours, by its nominal voltage. Therefore, Watt-hour (Wh) = ampere-hour (Ah) × volts (V).

* * * * *

■ 3. In § 171.12, paragraph (a)(6) is revised to read as follows:

§ 171.12 North American shipments.

(a) * * *

(6) *Lithium metal cells and batteries.* Lithium metal cells and batteries (UN3090) are forbidden for transport aboard passenger-carrying aircraft. The outside of each package that contains lithium cells or batteries meeting the conditions for exception in § 173.185(c) of this subchapter and transported in accordance with the Transport Canada TDG Regulations must be marked in accordance with § 173.185(c)(1)(iii) or (c)(1)(iv) as appropriate.

* * * * *

■ 4. In § 171.24, paragraphs (d)(1)(ii) and (d)(1)(iii) are revised to read as follows:

§ 171.24 Additional requirements for the use of the ICAO Technical Instructions.

* * * * *

(d) * * *

(1) * * *

(ii) *Lithium metal cells and batteries.* Lithium metal cells and batteries (UN3090) are forbidden for transport aboard passenger-carrying aircraft. The outside of each package that contains lithium metal cells or lithium metal batteries (UN3090) transported in accordance with Packing Instruction 968, Section II of the ICAO Technical Instructions must be marked “PRIMARY LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT” or “LITHIUM METAL BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT.”

(iii) *Low production runs or prototypes lithium cells or batteries.* Production runs consisting of not more

than 100 lithium cells or batteries per year, or prototype lithium cells or batteries (including cells or batteries packed with, or contained in, equipment or motor vehicles) not of a type proven to meet the requirements of section 38.3 of the UN Manual of Tests and Criteria (IBR, see § 171.7 of this subchapter), must be approved by the Associate Administrator prior to transportation aboard aircraft.

* * * * *

■ 5. In § 171.25, paragraph (b)(3) is revised to read as follows:

§ 171.25 Additional requirements for the use of the IMDG Code.

* * * * *

(b) * * *

(3) The outside of each package containing lithium metal cells or batteries (UN3090) transported in accordance with special provision 188 of the IMDG Code must be marked “PRIMARY LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT” or “LITHIUM METAL BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT.” This marking is not required on packages that contain 5 kg (11 pounds) net weight or less of lithium metal cells or batteries that are packed with, or contained in, equipment.

* * * * *

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, TRAINING REQUIREMENTS, AND SECURITY PLANS

■ 6. The authority citation for part 172 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.97.

■ 7. In § 172.101, the Hazardous Materials Table is amended by removing and adding entries in alphabetical order, to read as follows:

§ 172.101 Purpose and use of hazardous materials table.

* * * * *

[illegible]

■ 8. In § 172.102 amend paragraphs (c)(1) and (c)(2) as follows:

■ a. In paragraph (c)(1), special provisions 134 and 328 are revised and special provisions 29, 188, 189, and 190 are removed;

■ b. In paragraph (c)(2), special provisions A51, A54 and A101 are revised; and special provisions A55, A100, A103, and A104 are removed.

The revisions read as follows:

§ 172.102 Special provisions.

* * * * *

(c) * * *

(1) * * *

134 This entry only applies to vehicles powered by wet batteries, sodium batteries, lithium metal batteries or lithium ion batteries and equipment powered by wet batteries or sodium batteries that are transported with these batteries installed. For the purpose of this special provision, vehicles are self-propelled apparatus designed to carry one or more persons or goods. Examples of such vehicles are electrically-powered cars, motorcycles, scooters, three- and four-wheeled vehicles or motorcycles, battery-assisted bicycles, lawn tractors, boats, aircraft, wheelchairs and other mobility aids. Examples of equipment are lawnmowers, cleaning machines or model boats and model aircraft.

Equipment powered by lithium metal batteries or lithium ion batteries must be consigned under the entries “Lithium metal batteries contained in equipment” or “Lithium metal batteries packed with equipment” or “Lithium ion batteries contained in equipment” or “Lithium ion batteries packed with equipment” as appropriate. Self-propelled vehicles or equipment that also contain an internal combustion engine must be consigned under the entries “Engine, internal combustion, flammable gas powered” or “Engine, internal combustion, flammable liquid powered” or “Vehicle, flammable gas powered” or “Vehicle, flammable liquid powered,” as appropriate. These entries include hybrid electric vehicles powered by both an internal combustion engine and batteries. Additionally, self-propelled vehicles or equipment that contain a fuel cell engine must be consigned under the entries “Engine, fuel cell, flammable gas powered” or “Engine, fuel cell, flammable liquid powered” or “Vehicle, fuel cell, flammable gas powered” or “Vehicle, fuel cell, flammable liquid powered,” as appropriate. These entries include hybrid electric vehicles powered by a fuel cell engine, an internal combustion engine, and batteries.

* * * * *

328 When lithium metal or lithium ion batteries are contained in the fuel cell system, the item must be described under this entry and the appropriate entries for “Lithium metal batteries contained in equipment” or “Lithium ion batteries contained in equipment”.

(c) * * *

(2) * * *

Code/Special Provisions

* * * * *

A51 Irrespective of the quantity limitations specified in Column (9A) of the § 172.101 Table or § 175.75(c), the following aircraft batteries may be transported on passenger aircraft as cargo:

a. Wet cell batteries, UN 2794 or UN 2795, up to a limit of 100kg net mass per package;

b. Lithium ion batteries, UN 3480, packages containing a single aircraft battery with a net mass not exceeding 35kg; and

c. Transport in accordance with this special provision must be noted on the shipping paper.

* * * * *

A54 Irrespective of the quantity limits in Column 9B of the § 172.101 table, a lithium battery, including a lithium battery packed with, or contained in, equipment that otherwise meets the applicable requirements of § 173.185, may have a mass exceeding 35 kg if approved by the Associate Administrator prior to shipment.

* * * * *

A101 In addition to the applicable requirements of § 173.185, the quantity of lithium metal in the batteries contained in any piece of equipment must not exceed 12 g per cell and 500 g per battery.

* * * * *

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

■ 9. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.97.

■ 10. Section 173.185 is revised to read as follows:

§ 173.185 Lithium cells and batteries.

As used in this section, *lithium cell(s)* or *battery(ies)* includes both lithium metal and lithium ion chemistries.

Equipment means the device or apparatus for which the lithium cells or batteries will provide electrical power for its operation.

(a) *Classification.* (1) Each lithium cell or battery must be of the type proven to

meet the criteria in Part III, sub-section 38.3 of the UN Manual of Tests and Criteria (IBR; see § 171.7 of this subchapter). Lithium cells and batteries are subject to these tests regardless of whether the cells used to construct the battery are of a tested type.

(i) Cells and batteries manufactured according to a type meeting the requirements of sub-section 38.3 of the UN Manual of Tests and Criteria, Revision 3, Amendment 1 or any subsequent revision and amendment applicable at the date of the type testing may continue to be transported, unless otherwise provided in this subchapter.

(ii) Cell and battery types only meeting the requirements of the UN Manual of Tests and Criteria, Revision 3, are no longer valid. However, cells and batteries manufactured in conformity with such types before July 2003 may continue to be transported if all other applicable requirements are fulfilled.

(2) Each person who manufactures lithium cells or batteries must create a record of satisfactory completion of the testing required by this paragraph prior to offering the lithium cell or battery for transport and must:

(i) Maintain this record for as long as that design is offered for transportation and for one year thereafter; and

(ii) Make this record available to an authorized representative of the Federal, state or local government upon request.

(3) Except for cells or batteries meeting the requirements of paragraph (c) of this section, each lithium cell or battery must:

(i) Incorporate a safety venting device or be designed to preclude a violent rupture under conditions normally incident to transport;

(ii) Be equipped with effective means of preventing external short circuits; and

(iii) Be equipped with an effective means of preventing dangerous reverse current flow (e.g., diodes or fuses) if a battery contains cells, or a series of cells that are connected in parallel.

(b) *Packaging.* (1) Each package offered for transportation containing lithium cells or batteries, including lithium cells or batteries packed with, or contained in, equipment, must meet all applicable requirements of subpart B of this part.

(2) Lithium cells or batteries, including lithium cells or batteries packed with, or contained in, equipment, must be packaged in a manner to prevent:

(i) Short circuits;

(ii) Movement within the outer package; and

(iii) Accidental activation of the equipment.

(3) For packages containing lithium cells or batteries offered for transportation:

(i) The lithium cells or batteries must be placed in non-metallic inner packagings that completely enclose the cells or batteries, and separate the cells or batteries from contact with equipment, other devices, or conductive materials (e.g., metal) in the packaging.

(ii) The inner packagings containing lithium cells or batteries must be placed in one of the following packagings meeting the requirements of part 178, subparts L and M, of this subchapter at the Packing Group II level:

(A) Metal (4A, 4B, 4N), wooden (4C1, 4C2, 4D, 4F), fiberboard (4G), or solid plastic (4H1, 4H2) box;

(B) Metal (1A2, 1B2, 1N2), plywood (1D), fiber (1G), or plastic (1H2) drum;

(C) Metal (3A2, 3B2) or plastic (3H2) jerrican.

(iii) When packed with equipment lithium cells or batteries must:

(A) Be placed in inner packagings that completely enclose the cell or battery, then placed in an outer packaging. The completed package for the cells or batteries must meet the Packing Group II performance requirements as specified in paragraph (b)(3)(ii) of this section; or

(B) Be placed in inner packagings that completely enclose the cell or battery, then placed with equipment in a package that meets the Packing Group II performance requirements as specified in paragraph (b)(3)(ii) of this section.

(4) When lithium cells or batteries are contained in equipment:

(i) The outer packaging must be constructed of suitable material of adequate strength and design in relation to the capacity and intended use of the packaging, unless the lithium cells or batteries are afforded equivalent protection by the equipment in which they are contained;

(ii) Equipment must be secured against movement within the outer packaging and be packed so as to prevent accidental operation during transport; and

(iii) Any spare lithium ion cells or batteries packed with the equipment must be packaged in accordance with paragraph (b)(3) of this section.

(5) Lithium batteries that weigh 12 kg (26.5 pounds) or more and have a strong, impact-resistant outer casing and assemblies of such batteries, may be packed in strong outer packagings; in protective enclosures (for example, in fully enclosed or wooden slatted crates); or on pallets or other handling devices, instead of packages meeting the UN

performance packaging requirements in paragraphs (b)(3)(ii) and (b)(4) of this section. Batteries or battery assemblies must be secured to prevent inadvertent movement, and the terminals may not support the weight of other superimposed elements. Batteries or battery assemblies packaged in accordance with this paragraph are not permitted for transportation by passenger-carrying aircraft, and may be transported by cargo aircraft only if approved by the Associate Administrator.

(c) *Exceptions for smaller cells or batteries.* A package containing lithium cells or batteries, or lithium cells or batteries packed with, or contained in, equipment, that meets the conditions of this paragraph, is excepted from the requirements in subparts C through H of part 172 of this subchapter and the UN performance packaging requirements in paragraphs (b)(3)(ii) and (b)(4) of this section under the following conditions and limitations.

(1) *Size limits:*

(i) The Watt-hour rating may not exceed 20 Wh for a lithium ion cell or 100 Wh for a lithium ion battery. After December 31, 2015, each lithium ion battery subject to this provision must be marked with the Watt-hour rating on the outside case.

(ii) The lithium content may not exceed 1 g for a lithium metal cell or 2 g for a lithium metal battery.

(iii) Except when lithium metal cells or batteries are packed with or contained in equipment in quantities less than 5 kg net weight, the outer package that contains lithium metal cells or batteries must be marked: "PRIMARY LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT" or "LITHIUM METAL BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT."

(iv) For transportation by highway or rail only, the lithium content of the cell and battery may be increased to 5 g for a lithium metal cell and 25 g for a lithium metal battery and 60 Wh for a lithium ion cell or 300 Wh for a lithium ion battery provided the outer package is marked: "LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD AIRCRAFT AND VESSEL."

(v) The marking specified in paragraphs (c)(1)(ii) and (c)(1)(iii) of this section must have a background of contrasting color, and the letters in the marking must be:

(A) At least 6 mm (0.25 inch) on packages having a gross weight of 30 kg (66 pounds) or less, except that smaller font may be used as necessary when package dimensions so require.

(B) At least 12 mm (0.5 inch) in height on packages having a gross weight of more than 30 kg (66 pounds).

(vi) Except when lithium cells or batteries are packed with, or contained in, equipment, each package must not exceed 30 kg (66 pounds) gross weight.

(2) *Packaging.* Except when lithium cells or batteries are contained in equipment, each package must be capable of withstanding a 1.2 meter drop test, in any orientation, without damage to the cells or batteries contained in the package, without shifting of the contents that would allow battery-to-battery (or cell-to-cell) contact, and without release of the contents of the package.

(3) *Hazard communication.* Except for a package containing button cell batteries installed in equipment (including circuit boards), or no more than four lithium cells or two lithium batteries installed in the equipment:

(i) The outer package must be marked with:

(A) An indication that the package contains "lithium metal" or "lithium ion" cells or batteries, as appropriate;

(B) An indication that the package is to be handled with care and that a flammable hazard exists if the package is damaged;

(C) An indication that special procedures must be followed in the event the package is damaged, to include inspection and repacking if necessary;

(D) A telephone number for additional information.

(ii) Each shipment of one or more packages marked in accordance with this paragraph must be accompanied by a document that includes the following:

(A) An indication that the package contains "lithium metal" or "lithium ion" cells or batteries, as appropriate;

(B) An indication that the package is to be handled with care and that a flammable hazard exists if the package is damaged;

(C) An indication that special procedures must be followed in the event the package is damaged, to include inspection and repacking if necessary; and

(D) A telephone number for additional information.

(4) *Air transportation.* For transportation by aircraft, lithium cells and batteries may not exceed the limits in the following table. The limits on the maximum number of batteries and maximum net quantity of batteries in the following table may not be combined in the same package:

Contents	Lithium metal cells and/or batteries with a lithium content not more than 0.3 g	Lithium metal cells with a lithium content more than 0.3 g but not more than 1 g	Lithium metal batteries with a lithium content more than 0.3 g but not more than 2 g	Lithium ion cells and/or batteries with a Watt-hour rating not more than 2.7 Wh	Lithium ion cells with a Watt-hour rating more than 2.7 Wh but not more than 20 Wh	Lithium ion batteries with a Watt-hour rating more than 2.7 Wh but not more than 100 Wh
Maximum number of cells/batteries per package.	No Limit	8 cells	2 batteries	No Limit	8 cells	2 batteries.
Maximum net quantity (mass) per package.	2.5 kg	n/a	n/a	2.5 kg	n/a	n/a.

(i) The outer package must be durably and legibly marked with the following handling marking, which is durable, legible and displayed on a background of contrasting color:



(A) The marking must be not less than 120 mm (4.7 inches) wide by 110 mm (4.3 inches) high except markings of 105 mm (4.1 inches) wide by 74 mm (2.9 inches) high may be used on a package containing lithium batteries when the package is too small for the larger marking;

(B) The symbols and letters must be black and the border must be red;

(C) The “*” must be replaced by “lithium ion battery” and/or “Lithium metal battery” as appropriate and the “xxx-xxx-xxxx” must be replaced by a telephone number for additional information; and

(D) When packages required to bear the handling marking are placed in an overpack, the handling marking must either be clearly visible through the overpack, or the handling marking must also be affixed on the outside of the overpack, and the overpack must be marked with the word “Overpack”.

(ii) Each shipment with packages required to bear the handling marking must include an indication the shipment contains “lithium ion batteries” or “lithium metal batteries,”

as appropriate, and when an air waybill is used, an indication on the air waybill of compliance with this paragraph (c)(4) (or the applicable ICAO Packing Instruction).

(iii) For lithium batteries packed with, or contained in, equipment, the number of batteries in each package is limited to the minimum number required to power the piece of equipment, plus two spares, and the total net quantity (mass) of the lithium cells or batteries in the completed package must not exceed 5 kg.

(iv) Each person who prepares a package for transport containing lithium cells or batteries, including cells or batteries packed with, or contained in, equipment in accordance with the conditions and limitations in this paragraph, must receive adequate instruction on these conditions and limitations, commensurate with their responsibilities.

(v) A package that exceeds the number or quantity (mass) limits in the table shown in this paragraph (c)(4) is subject to all applicable requirements of this subchapter, except that a package

containing no more than 2.5 kg lithium metal cells or 10 kg lithium ion cells or batteries is not subject to:

(A) The UN performance packaging requirements in paragraphs (b)(3)(ii) of this section when the package displays both the lithium battery handling marking and the Class 9 label; and

(B) The shipping paper requirements of subpart C of part 172 when the offeror provides the air carrier alternative written documentation containing the name and address of the offeror and consignee, the UN number, an indication of compliance with this paragraph (c)(4) applies (or the applicable ICAO Packing Instruction), and the number of packages and the gross mass of each package and notification is given to the pilot-in-command in accordance with § 175.33 of this subchapter.

(d) *Lithium cells or batteries shipped for disposal or recycling.* A lithium cell or battery, including a lithium cell or battery contained in equipment, that is transported by motor vehicle to a permitted storage facility or disposal site, or for purposes of recycling, is

excepted from the testing and record keeping requirements of paragraph (a) and the specification packaging requirements of paragraph (b)(3) of this section, when packed in a strong outer packaging conforming to the requirements of §§ 173.24 and 173.24a. A lithium cell or battery that meets the size, packaging, and hazard communication conditions in paragraph (c)(1)–(3) of this section is excepted from subparts C through H of part 172 of this subchapter.

(e) *Low production runs and prototypes.* Low production runs (i.e., annual production runs consisting of not more than 100 lithium cells or batteries), or prototype lithium cells or batteries transported for purposes of testing, are excepted from the testing and record keeping requirements of paragraph (a) of this section provided:

(1) Except as provided in paragraph (e)(3) of this section, each cell or battery is individually packed in a non-metallic inner packaging, inside an outer packaging, and is surrounded by cushioning material that is non-combustible and non-conductive;

(2) The inner packages containing lithium cells or batteries are packed in one of the following packagings that meet the requirements of part 178, Subparts L and M at Packing Group I level.

(i) Metal (4A, 4B, 4N), wooden (4C1, 4C2, 4D, 4F), or solid plastic (4H2) box;

(ii) Metal (1A2, 1B2, 1N2), plywood (1D), or plastic (1H2) drum.

(3) Lithium batteries that weigh 12 kg (26.5 pounds) or more and have a strong, impact-resistant outer casing or assemblies of such batteries, may be packed in strong outer packagings, in protective enclosures (for example, in fully enclosed or wooden slatted crates), or on pallets or other handling devices, instead of packages meeting the UN performance packaging requirements in paragraphs (b)(3)(ii) and (b)(4) of this section. The battery or battery assembly must be secured to prevent inadvertent movement, and the terminals may not support the weight of other superimposed elements;

(4) Irrespective of the limit specified in column (9B) of the § 172.101 Hazardous Materials Table, the battery or battery assembly prepared for transport in accordance with this paragraph may have a mass exceeding 35 kg gross weight when transported by cargo aircraft; and

(5) Batteries or battery assemblies packaged in accordance with this paragraph are not permitted for transportation by passenger-carrying aircraft, and may be transported by cargo aircraft only if approved by the

Associate Administrator prior to transportation.

(f) *Damaged, defective, or recalled cells or batteries.* Lithium cells or batteries, that have been damaged or identified by the manufacturer as being defective for safety reasons, that have the potential of producing a dangerous evolution of heat, fire, or short circuit (e.g. those being returned to the manufacturer for safety reasons) may be transported by highway, rail or vessel only, and must be packaged as follows:

(1) Each cell or battery must be placed in individual, non-metallic inner packaging that completely encloses the cell or battery;

(2) The inner packaging must be surrounded by cushioning material that is non-combustible, non-conductive, and absorbent; and

(3) Each inner packaging must be individually placed in one of the following packagings meeting the requirements of part 178, subparts L and M, of this subchapter at the Packing Group I level:

(i) Metal (4A, 4B, 4N), wooden (4C1, 4C2, 4D, 4F), or solid plastic (4H2) box;

(ii) Metal (1A2, 1B2, 1N2), plywood (1D), or plastic (1H2) drum; and

(4) The outer package must be marked with an indication that the package contains a “Damaged/defective lithium ion battery” and/or “Damaged/defective lithium metal battery” as appropriate.

(g) *Approval.* A lithium cell or battery that does not conform to the provisions of this subchapter may be transported only under conditions approved by the Associate Administrator.

■ 11. In § 173.219, paragraph (b)(3) is revised to read as follows:

§ 173.219 Life-saving appliances.

* * * * *

(b) * * *

(3) Electric storage batteries and lithium batteries (life-saving appliances containing lithium batteries must be packed in accordance with § 173.185 and Special Provisions A54 and A101 as applicable.);

* * * * *

■ 12. In § 173.220, paragraphs (d) and (f)(1) are revised to read as follows:

§ 173.220 Internal combustion engines, self-propelled vehicles, mechanical equipment containing internal combustion engines, battery powered equipment or machinery, fuel cell-powered equipment or machinery.

* * * * *

(d) *Lithium batteries.* Except as provided in § 172.102, special provision A101, of this subchapter, vehicles, engines, and machinery powered by lithium metal batteries, that are

transported with these batteries installed, are forbidden aboard passenger-carrying aircraft. Lithium batteries contained in vehicles, engines, or mechanical equipment must be securely fastened in the battery holder of the vehicle, engine, or mechanical equipment, and be protected in such a manner as to prevent damage and short circuits (e.g., by the use of non-conductive caps that cover the terminals entirely). Except for vehicles transported by highway, rail, or vessel with prototype or low production lithium batteries securely installed, each lithium battery must be of a type that has successfully passed each test in the UN Manual of Tests and Criteria, as specified in § 173.185, unless approved by the Associate Administrator.

* * * * *

(f) *Other hazardous materials.* (1) Items containing hazardous materials, such as fire extinguishers, compressed gas accumulators, safety devices, and other hazardous materials that are integral components of the motor vehicle, engine, or mechanical equipment, and that are necessary for the operation of the vehicle, engine, or mechanical equipment, or for the safety of its operator or passengers, must be securely installed in the motor vehicle, engine, or mechanical equipment. Such items are not otherwise subject to the requirements of this subchapter. Equipment (other than vehicles, engines, or mechanical equipment), such as consumer electronic devices containing lithium batteries, must be described as “Lithium metal batteries contained in equipment” or “Lithium ion batteries contained in equipment,” as appropriate, and transported in accordance with § 173.185 of this subchapter, and applicable special provisions. Equipment (other than vehicles, engines, or mechanical equipment), such as consumer electronic devices containing fuel cells (fuel cell cartridges), must be described as “Fuel cell cartridges contained in equipment” and transported in accordance with § 173.230 of this subchapter.

* * * * *

PART 175—CARRIAGE BY AIRCRAFT

■ 13. The authority citation for part 175 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.97.

■ 14. In § 175.8, add a new paragraph (a)(4) to read as follows:

§ 175.8 Exceptions for operator equipment and items of replacement.

(a) * * *
(4) Unless otherwise addressed by FAA regulation or policy (e.g. Advisory Circular), hazardous materials used by the operator aboard the aircraft, when approved by the Administrator of the Federal Aviation Administration.

* * * * *

■ 15. In § 175.10, paragraph (a)(18) is revised to read as follows:

§ 175.10 Exceptions for passengers, crewmembers, and air operators.

(a) * * *
(18) Except as provided in § 173.21 of this subchapter, portable electronic devices (e.g., watches, calculating machines, cameras, cellular phones, laptop and notebook computers, camcorders, medical devices etc.) containing dry cells or dry batteries (including lithium cells or batteries) and spare dry cells or batteries for these devices, when carried by passengers or crew members for personal use. Portable electronic devices powered by lithium batteries may be carried in either checked or carry-on baggage. Spare lithium batteries must be carried in carry-on baggage only. Each installed or spare lithium battery must be of a type proven to meet the requirements of each test in the UN Manual of Tests and Criteria, Part III, Sub-section 38.3 and

each spare lithium battery must be individually protected so as to prevent short circuits (e.g., by placement in original retail packaging, by otherwise insulating terminals by taping over exposed terminals, or placing each battery in a separate plastic bag or protective pouch). In addition, each installed or spare lithium battery must not exceed the following:

- (i) For a lithium metal battery, a lithium content of not more than 2 grams per battery; or
- (ii) For a lithium ion battery, the Watt-hour rating must not exceed 100 Wh. With the approval of the operator, portable electronic devices may contain lithium ion batteries exceeding 100 Wh, but not exceeding 160 Wh and no more than two individually protected lithium ion batteries each exceeding 100 Wh, but not exceeding 160 Wh, may be carried per person as spare batteries in carry-on baggage.

* * * * *

■ 16. In § 175.30, add a new paragraph (a)(5) to read as follows:

§ 175.30 Inspecting shipments.

(a) * * *
(5) Described on alternative written documentation when authorized in accordance with § 173.185(c)(4)(v). See § 175.33 for alternative written documentation retention requirements.

* * * * *

■ 17. In § 175.33, add new paragraphs (a)(12) and (c)(5) to read as follows:

§ 175.33 Shipping paper and notification of pilot-in-command.

(a) * * *

(12) For shipments of lithium cells or batteries (UN3090 or UN3480) offered for transportation, or transported in accordance with § 173.185(c)(4)(v) of this subchapter, only the UN Number, proper shipping name, hazard class, and the total quantity at each specific loading location and whether the package must be loaded on a cargo only aircraft.

* * * * *

(c) * * *

(5) Retain a copy of the alternative written documentation when provided in accordance with § 173.185(c)(4)(v)(B) of this subchapter or an electronic image thereof, or the information contained therein for 90 days at the airport of departure or the operator's principal place of business.

* * * * *

Issued in Washington, DC, on July 29, 2014 under authority delegated in 49 CFR part 1.97.

Cynthia L. Quarterman,
Administrator.

[FR Doc. 2014-18146 Filed 8-5-14; 8:45 am]

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Part V

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Withdrawal of the Proposed Rules To List Graham's Beardtongue (*Penstemon grahamii*) and White River Beardtongue (*Penstemon scariosus* var. *albifluvis*) and Designate Critical Habitat; Proposed Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-R6-ES-2013-0081;
Docket No. FWS-R6-ES-2013-0082;
4500030113]

RIN 1018-AY95; 1018-AZ61

Endangered and Threatened Wildlife and Plants; Withdrawal of the Proposed Rules To List Graham's Beardtongue (*Penstemon grahamii*) and White River Beardtongue (*Penstemon scariosus* var. *albifluvis*) and Designate Critical Habitat

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rules; withdrawal.

SUMMARY: We, the U.S. Fish and Wildlife Service, withdraw the proposed rule to list Graham's beardtongue (*Penstemon grahamii*) and White River beardtongue (*Penstemon scariosus* var. *albifluvis*) as threatened species throughout their ranges under the Endangered Species Act of 1973, as amended. This withdrawal is based on our conclusion that the threats to the species as identified in the proposed rule no longer are as significant as we previously determined. We base this conclusion on our analysis of new information concerning current and future threats and conservation efforts. We find the best scientific and commercial data available indicate that the threats to the species and their habitats have been reduced so that the two species no longer meet the statutory definition of threatened or endangered species. Therefore, we are withdrawing both our proposed rule to list these species as threatened species and our proposed rule to designate critical habitat for these species.

DATES: The proposed rules published on August 6, 2013 (78 FR 47590 and 78 FR 47832), are withdrawn as of August 6, 2014.

ADDRESSES: The withdrawal of our proposed rules and supplementary documents are available on the Internet at <http://www.regulations.gov> at Docket Nos. FWS-R6-ES-2013-0081 and FWS-R6-ES-2013-0082, and at <http://www.fws.gov/mountain-prairie/species/plants/2utahbeardtongues/>. Comments and materials received, as well as supporting documentation used in the preparation of these withdrawals, are also available for public inspection, by appointment, during normal business hours at: U.S. Fish and Wildlife Service, Utah Ecological Services Field Office,

2369 West Orton Circle, Suite 50, West Valley City, Utah 84119; telephone 801-975-3330.

FOR FURTHER INFORMATION CONTACT:

Larry Crist, Field Supervisor, U.S. Fish and Wildlife Service, Utah Ecological Services Field Office, 2369 West Orton Circle, Suite 50, West Valley City, UT 84119; by telephone at 801-975-3330. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800-877-8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish this document. Under the Endangered Species Act (Act), if a species is determined to be an endangered or threatened species throughout all or a significant portion of its range, we are required to promptly publish a proposal in the **Federal Register** and make a determination on our proposal within 1 year. On August 6, 2013, we issued proposed rules to list Graham's beardtongue and White River beardtongue as threatened species and to designate critical habitat because we determined there were threats from energy development, and cumulative threats from livestock grazing, invasive weeds, small population sizes, and climate change (78 FR 47590 and 78 FR 47832). However, this document withdraws our proposed rules to list the Graham's beardtongue and White River beardtongue as threatened species under the Act and designate critical habitat for these species because we have now determined that the threats to the two species have been reduced such that listing is not warranted.

The basis for our action. Under the Act, we can determine that a species is an endangered or threatened species based on any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) Overutilization for commercial, recreational, scientific, or educational purposes; (C) Disease or predation; (D) The inadequacy of existing regulatory mechanisms; or (E) Other natural or manmade factors affecting its continued existence. We have determined that the threats to the two species have been reduced such that listing is not warranted. Therefore, this document withdraws our proposed rules to list the Graham's beardtongue and White River beardtongue as threatened species under the Act and designate critical habitat.

Peer review and public comment. We sought expert opinion from several appropriate and independent specialists

to ensure that our proposed rules were based on scientifically sound data, assumptions, and analyses. We invited these peer reviewers to comment on our listing and critical habitat proposals. We also considered all comments and information received during the comment periods.

Background—Graham's Beardtongue

Previous Federal Actions

For a detailed description of Federal actions concerning Graham's beardtongue, please refer to our January 19, 2006, proposed rule to list the species and designate critical habitat (71 FR 3158); our December 19, 2006, withdrawal of the proposed rule to list the species and designate critical habitat (71 FR 76024); and our August 6, 2013 proposed rules to list the species and designate critical habitat (78 FR 47590; 78 FR 47832). In the document we published on December 19, 2006 (71 FR 76024), we addressed public comments, analyzed available data, and withdrew the proposed listing and critical habitat rule for Graham's beardtongue that we published on January 19, 2006 (71 FR 3158), concluding that threats to Graham's beardtongue, particularly energy development, were not as significant as previously believed and were not likely to endanger the species in the foreseeable future throughout all or a significant portion of its range.

On December 16, 2008, the Center for Native Ecosystems, Southern Utah Wilderness Alliance, Utah Native Plant Society (UNPS), and Colorado Native Plant Society filed a complaint in the United States District Court for the District of Colorado challenging the withdrawal of our proposal to list Graham's beardtongue. The court ruled in favor of the plaintiffs on June 9, 2011, vacating our December 2006 withdrawal and reinstating our January 2006 proposed rule.

In 2007, the Service, Bureau of Land Management (BLM), Uintah County, Utah Department of Natural Resources (DNR) and Utah School and Institutional Trust Lands Administration (SITLA) drafted a Conservation Agreement (CA) for the conservation of Graham's beardtongue and its ecosystem. Although this agreement was not signed by all parties and only partially implemented, several of the parties contributed to the conservation of the species in the spirit of the agreement. In particular, BLM signed the agreement and fulfilled their commitments by funding surveys, monitoring for plant demographics, funding a population viability analysis, and avoiding and minimizing impacts to

the species and its habitat from surface disturbances (Service 2007, pp. 11–12). Uintah County and Utah DNR also funded surveys for the species from 2008 to 2010.

The best available information for Graham's beardtongue has changed considerably since our January 2006 proposed rule was written and withdrawn. On August 6, 2013, we published a revised proposed listing rule (78 FR 47590) and a proposed critical habitat rule to reflect new information regarding Graham's beardtongue (78 FR 47832). In these same rules we also proposed to list and designate critical habitat for White River beardtongue. Upon publication of our proposed rules, we opened a 60-day comment period that closed on October 7, 2013.

Following publication of our proposed rules, the same parties that drafted the 2007 CA for Graham's beardtongue reconvened to evaluate species' surveys and distribution information and reassess the conservation needs of both the White River and Graham's beardtongues. Based on this evaluation, the parties completed a new conservation agreement (2014 CA, entire) that specifically addresses the threats identified in our 2013 proposed rule to list the two species (78 FR 47590, August 6, 2013). In the 2014 CA, the parties committed to conservation actions including establishing 17,957 hectares (ha) (44,373 acres (ac)) of occupied and unoccupied suitable habitat as protected conservation areas with limited surface disturbance and avoidance of plants by 91.4 m (300 ft). Additionally, the BLM agreed to avoid surface disturbances within 91.4 m (300 ft) of Graham's and White River beardtongue plants within and outside of conservation areas on BLM land (see Summary of Factors Affecting the Species, Energy Exploration and Development and Ongoing and Future Conservation Efforts). The parties also developed conservation measures to address the cumulative impacts from livestock grazing, invasive weeds, small population sizes, and climate change by continuing species monitoring, monitoring climate, reducing impacts from grazing when and where detected, and controlling invasive weeds (see Summary of Factors Affecting the Species, Cumulative Effects from All Factors and Ongoing and Future Conservation Efforts). The 2014 CA is discussed in detail below.

On May 6, 2014 (79 FR 25806), we announced the reopening of the public

comment period on our August 6, 2013, proposed listing and proposed designation of critical habitat rules. At that time we also announced the availability of a draft economic analysis (DEA), a draft environmental assessment (EA), the draft 2014 CA, and an amended required determinations section of the proposal (78 FR 47590). We also announced the availability of 2013 survey results for the plants and our intent to hold a public information meeting and public hearing on May 28, 2014, in Vernal, Utah (79 FR 25806).

Species Information

Taxonomy and Species Description

Graham's beardtongue was described as a species in 1937 as an herbaceous perennial plant in the plantain family (Plantaginaceae). For most of the year when the plant is dormant, it exists as a small, unremarkable basal rosette of leaves. During flowering, the plant becomes a "gorgeous, large-flowered penstemon" (Welsh *et al.* 2003, p. 625). Similar to other species in the beardtongue (*Penstemon*) genus, Graham's beardtongue has a strongly bilabiate (two-lipped) flower with a prominent infertile staminode (sterile male flower part)—the "beardtongue" that typifies the genus. The combination of its large, vivid pink flower and densely bearded staminode with short, stiff, golden-orange hairs makes Graham's beardtongue quite distinctive. Each year an individual plant can produce one to a few flowering stems that can grow up to 18 centimeters (cm) (7.0 inches (in)) tall (with some exceptions), with 1 to 20 or more flowers on each flowering stem.

Distribution and Trends

When we published the proposed listing rule in 2006, there were 109 plant records, or "points," across Graham's beardtongue's known range, and the total species' population size was estimated at 6,200 individuals. Point data represent a physical location where one or more plants were observed on the ground. Point data are usually collected by GPS and stored as a "record" in a geographic information system database.

Since 2006, BLM, Uintah County, the Utah and Colorado Natural Heritage Programs and several private parties have completed many surveys for this species. The range of Graham's beardtongue is essentially the same as it was in 2006: A horseshoe-shaped band about 129 kilometers (80 miles) long and 9.6 km (6 mi) wide extending from the extreme southeastern edge of

Duchesne County in Utah to the northwestern edge of Rio Blanco County in Colorado (Figure 1). However, over the last 7 years we have identified larger numbers of plants and a greater distribution of the species across its range. We now know of 5,076 points representing 40,333 plants—over six times the number of plants known at the time of our 2006 proposed rule and 8,631 more plants than known at the time of our 2013 proposed rule (BLM 2013d, UNHP 2013b, CNHP 2014). Although the overall number of known plants has increased with additional surveys, this does not mean the total population is increasing. Rather, many parties have surveyed a greater area and now have a more complete picture of how many total Graham's beardtongue individuals exist. We assume that the current known range of this species has not changed substantially from what it was historically, because even though we have found more plants, the boundaries of the known range of the species have not changed.

We mapped all plant points, including those from new 2013 survey data, and grouped them into populations (Figure 1). First, we followed standardized methods used by the national network of Natural Heritage Programs to identify the species' element occurrences (EO). EOs are plant points that are grouped together based on geographic proximity (NatureServe 2004, p. 6). Natural Heritage Program criteria (NatureServe 2004, p. 6) classify points into discrete EOs if they are within 2 km (1.2 mi) of each other and separated by suitable habitat. We did not always have specific habitat suitability information and in these cases relied on the 2 km (1.2 mi) distance as our primary classification factor. Next, we included updated survey information collected from 2006 to the present and determined the number of distinct EOs. At the time of our 2013 proposed rule, we had documented 24 EOs: 20 in Utah and 4 in Colorado. An additional 8,631 plants found in the 2013 field season were added to our EO mapping in 2014, which added five new populations and merged several other populations together, resulting in no change to the total number of populations (Figure 1). For the purpose of this document, we consider EOs to be synonymous with populations and hereafter will use the term "populations" when describing the distribution of the species.

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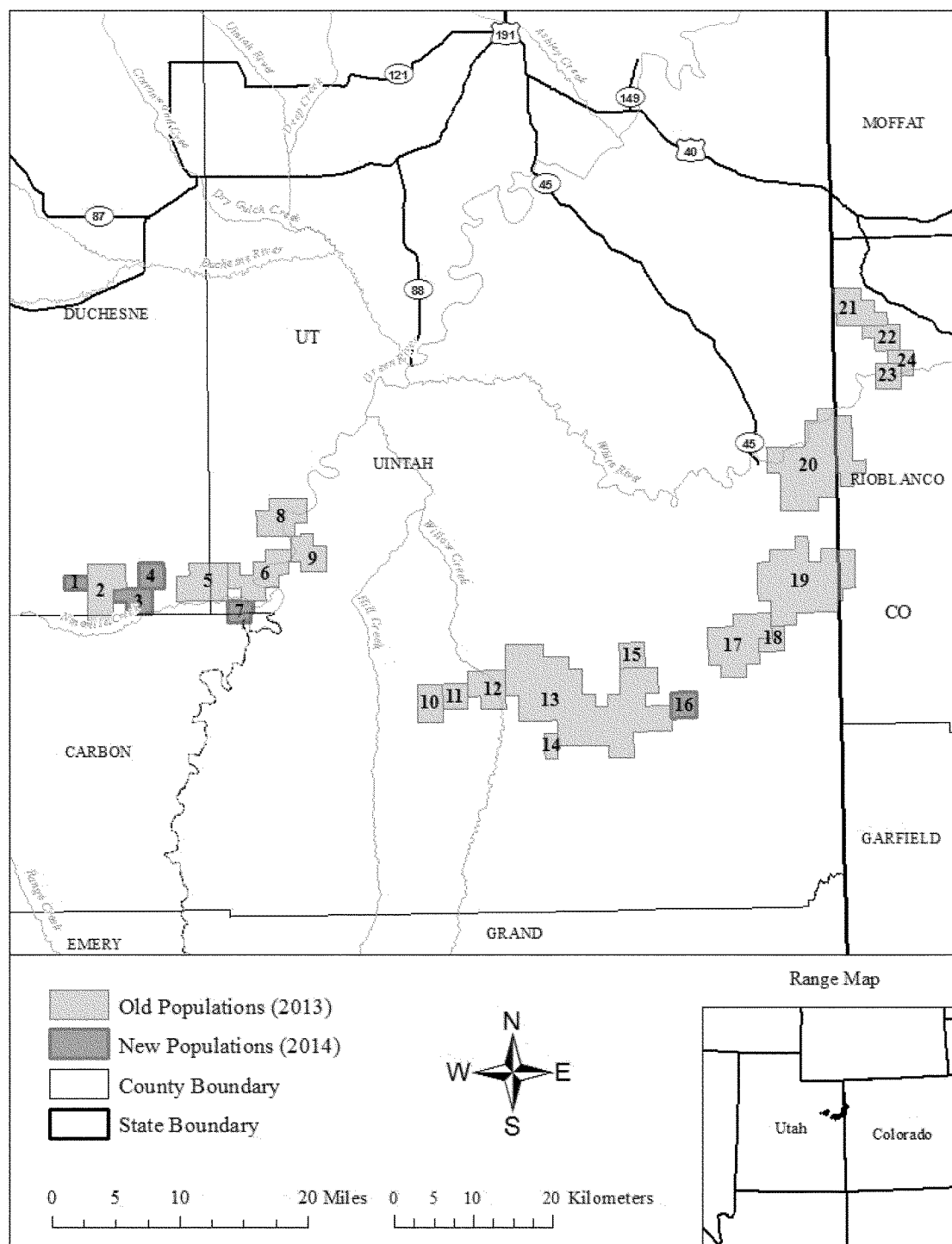


Figure 1. Graham's beardtongue's range.

Our understanding of the distribution of plants among populations has changed slightly since our 2013 proposed rule, reflecting the additional plants found during the 2013 surveys. We now estimate that one population (referred to as population 20) comprises about 18.3 percent of the species' total

population, compared to our estimate of 23 percent in 2012. Population 19 contains the most plants with 27.8 percent of the entire population. Populations 19, 17, 13 and 20 combined comprise 91 percent of the known number of plants. In 2006 and 2013, we noted that population 20 was an

important connectivity link between the Utah and Colorado populations of this species, and we still consider this to be true, especially given the large number of plants found in this population.

Approximately 52 percent of the total known population of Graham's beardtongue occurs on BLM-managed

lands, with the remainder on non-Federal lands with State and private ownership (Table 1). A land exchange between the BLM and the State of Utah

planned for 2014 will decrease the number of known plants on Federal lands and increase the plants on State lands by 2.2 percent (see Inadequacy of

Existing Regulatory Mechanisms, below).

TABLE 1—NUMBER OF INDIVIDUALS OF GRAHAM'S BEARDTONGUE BY LANDOWNER

[* Data as presented in the 2013 proposed rule includes surveys through 2012; ** Data as presented in this 2014 withdrawal includes surveys through 2013.]

	Number of individuals (2013 proposed rule)*	Percent of total (2013 proposed rule)*	Number of individuals (2014)**	Percent of total (2014)**
Federal	18,678	59	19,986	49.6
Private	8,137	26	8,525	21.1
State	4,887	15	11,822	29.3
Tribal	0	0	0	0
Total	31, 702	100	40,333	100

Population monitoring for Graham's beardtongue has been restricted to a handful of sites, thus limiting our knowledge of the population trend throughout its range. Our long-term monitoring information comes from two Graham's beardtongue sites in Utah within population 13 (see Figure 1) from 2004 to 2012, two additional sites within population 13 from 2010 to 2012, and one site in Colorado. The population 13 sites were stable and perhaps slowly increasing with a stochastic population growth rate just above one (McCaffery 2013a, p. 15). Recruitment and flowering for these Utah sites was low and sporadic, indicating that conditions were not always suitable for flowering to occur (McCaffery 2013a, p. 9). Although these two sites were stable, we do not know if this represents the trend of every population of the species across its range. The Colorado monitoring site showed that plant density remained similar between the 1986 to 1990 monitoring effort, and a renewed monitoring effort in 2005. In addition, the number of plants increased between 2009 to 2011 (BLM 2011, p. 6–7) but was lower in both years than the number counted in 2005. Small population sizes and low recruitment make this species more vulnerable to stochastic events, and without concerted conservation efforts, changes in stressors or habitat conditions may negatively impact the long-term growth of these sites (McCaffery 2013a, p. 19).

No link was found between reproduction and precipitation on a regional level, but it is likely that we do not completely understand the environmental factors affecting reproduction and survival (McCaffery 2013a, p. 16). A combination of several factors could be affecting population dynamics of Graham's beardtongue. For example, herbivory and climate could

interact to influence reproduction. Plants at the Blue Knoll study site were negatively impacted by herbivory from tiger moth caterpillars (possibly *Arctia caja utahensis*) (see Grazing, below), but a cool, wet spring in 2011 may have reduced herbivory on reproductive plants (Dodge and Yates 2011, pp. 7–8). Further studies are necessary to determine if herbivory or other factors are driving population dynamics of this species.

Habitat

Graham's beardtongue is an endemic plant found mostly in exposed oil shale strata of the Parachute Creek Member and other unclassified members of the Green River geologic formation including the Douglas Creek Member. Most populations are associated with the surface exposure of the petroleum-bearing oil shale Mahogany ledge (Shultz and Mutz 1979, p. 40; Neese and Smith 1982, p. 64). Soils at these sites are shallow with virtually no soil horizon development, and the surface is usually covered with broken shale chips or light clay derived from the thinly bedded shale. Based on data up to 2012, about a third of all known point locations of plants in our files grow on slopes that are 10 degrees or less, with an average slope across all known points of 17.6 degrees (Service 2013, p. 2). The species occurs at an average elevation of 1,870 meters (m) (6,134 feet (ft)), with a range in elevation from 1,426 to 2,128 m (4,677 to 6,982 ft) (Service 2013, p. 4). Individuals of Graham's beardtongue usually grow on southwest-facing exposures (Service 2013, p. 1).

Graham's beardtongue is associated with a suite of species similarly adapted to xeric (very dry) growing conditions on highly basic calcareous shale soils, including saline wildrye (*Leymus salinus*), mountain thistle (*Cirsium*

eatonii var. *eriocephalum*), spiny greasebush (*Glossopetalon spinescens* var. *meionandra*), Utah juniper (*Juniperus osteosperma*), two-needle piñon (*Pinus edulis*), and shadscale saltbush (*Atriplex confertifolia*) (UNHP 2013a, entire). Graham's beardtongue co-occurs with eight other rare species that are similarly endemic and restricted to the Green River Formation, including White River beardtongue. Other beardtongue species growing in the vicinity of Graham's beardtongue include thicket beardtongue (*Penstemon pachyphyllus*) and Fremont's beardtongue (*Penstemon fremontii*) (Fitts and Fitts 2008, pp. 13–28; Fitts and Fitts 2009, pp. 11–26; Fitts 2010, pp. 15–21; Fitts 2014, entire.), and these are likely important for supporting pollinators.

At higher elevations, Graham's beardtongue is found within sparse pinon-juniper woodland plant communities and on canyon rims. At lower elevations Graham's beardtongue is associated with a sparse desert shrubland dominated by shadscale saltbush.

Biology

Graham's beardtongue individuals live at least 10 years and likely longer; however, we do not know the plant's average life span (Service 2012a, p. 2). Graham's beardtongue is not as genetically diverse as other common, widespread beardtongues from the same region (Arft 2002, p. 5). However, populations 1 through 9 (see Figure 1) have minor morphological differences from the rest of the Graham's beardtongue populations (Shultz and Mutz 1979, p. 41) and may, due to geographic isolation, be genetically divergent from the remainder of the species' population, although this hypothesis has never been tested.

Graham's beardtongue usually flowers for a short period of time in late April through late June. Pollinators and flower visitors of Graham's beardtongue include the bees *Anthophora lesquerellae*, *Osmia sanrafaelae*, *Osmia rawlini*, the sweat bees *Lasioglossum sisymbrii* and *Dialictus* sp., and the masarid wasp *Pseudomasaris vespoides*, which is thought to be the primary pollinator for Graham's beardtongue (Lewinsohn and Tepedino 2007, p. 245; Dodge and Yates 2008, p. 30). At least one large pollinator, Hunt's bumblebee (*Bombus huntii*), is known to visit Graham's beardtongue (71 FR 3158, January 19, 2006), which is not unexpected due to the relatively large size of Graham's beardtongue's flowers compared to other beardtongues.

Graham's beardtongue has a mixed mating system, meaning individuals of this species can self-fertilize, but they produce more seed when they are cross-pollinated (Dodge and Yates 2009, p. 18). Thus, pollinators are important for maximum seed and fruit production. Based on the size of the largest Graham's beardtongue pollinators (i.e., Hunt's bumblebee), we expect pollinators are capable of travelling and transporting pollen for distances of at least 700 m (2,297 ft) (Service 2012b, pp. 8, 12). Therefore, maintaining sufficiently large numbers of reproducing plants with sufficient connectivity across the species' population distribution ensures cross-pollination, preserves genetic diversity, and prevents inbreeding depression (Dodge and Yates 2009, p. 18). Pollinators need a diversity of native plants for foraging, nesting, and egg-laying sites, and undisturbed places for overwintering (Shepherd *et al.* 2003, pp. 49–50). Thus, it is important to protect vegetation diversity within and around Graham's beardtongue populations to maintain a diversity of pollinators.

Background—White River Beardtongue

Previous Federal Actions

On November 28, 1983, White River beardtongue was designated as a category 1 candidate under the

Endangered Species Act of 1973, as amended (Act) (48 FR 53640). Category 1 candidate species were defined as “those species for which the Service has on file sufficient information on biological vulnerability and threat(s) to support issuance of a proposed rule to list but issuance of the proposed rule is precluded” (61 FR 7597, February 28, 1996). In the February 1996 candidate notice of review (CNOR) (61 FR 7596), we abandoned the use of numerical category designations and changed the status of White River beardtongue to a candidate under the current definition. We maintained White River beardtongue as a candidate species in subsequent updated CNORs up through the publication of the 2013 proposed rule to list the species.

On September 9, 2011, we reached an agreement with plaintiffs in Endangered Species Act Section 4 Deadline Litig., Misc. Action No. 10–377 (EGS), MDL Docket No. 2165 (D. DC) to systematically review and address the needs of all species listed in our 2010 CNOR, which included White River beardtongue. On August 6, 2013, we published a proposed rule to list Graham's and White River beardtongues and a proposed rule to designate critical habitat for both species (78 FR 47590; 78 FR 47832). As explained above in Background—Graham's beardtongue, *Previous Federal Actions*, a new conservation agreement was completed (2014 CA, entire) to specifically address the threats identified in our 2013 proposed rule. This conservation agreement along with the economic analysis of our 2013 proposed critical habitat designation and other supporting documents were made available for public review and comment as described above in Background—Graham's beardtongue, *Previous Federal Actions*.

Species Information

Taxonomy and Species Description

White River beardtongue is in the plantain family (Plantaginaceae). It is an herbaceous, shrubby plant with showy lavender flowers. It grows up to 50 cm

(20 in) tall, with multiple clusters of upright stems. It has long, narrow, green leaves. Like other members of the beardtongue genus, including Graham's beardtongue, White River beardtongue has a strongly bilabiate (two-lipped) flower with a prominent infertile staminode (sterile male flower part), or “beardtongue.” Blooming occurs from May into early June, with seeds produced by late June (Lewinsohn 2005, p. 9).

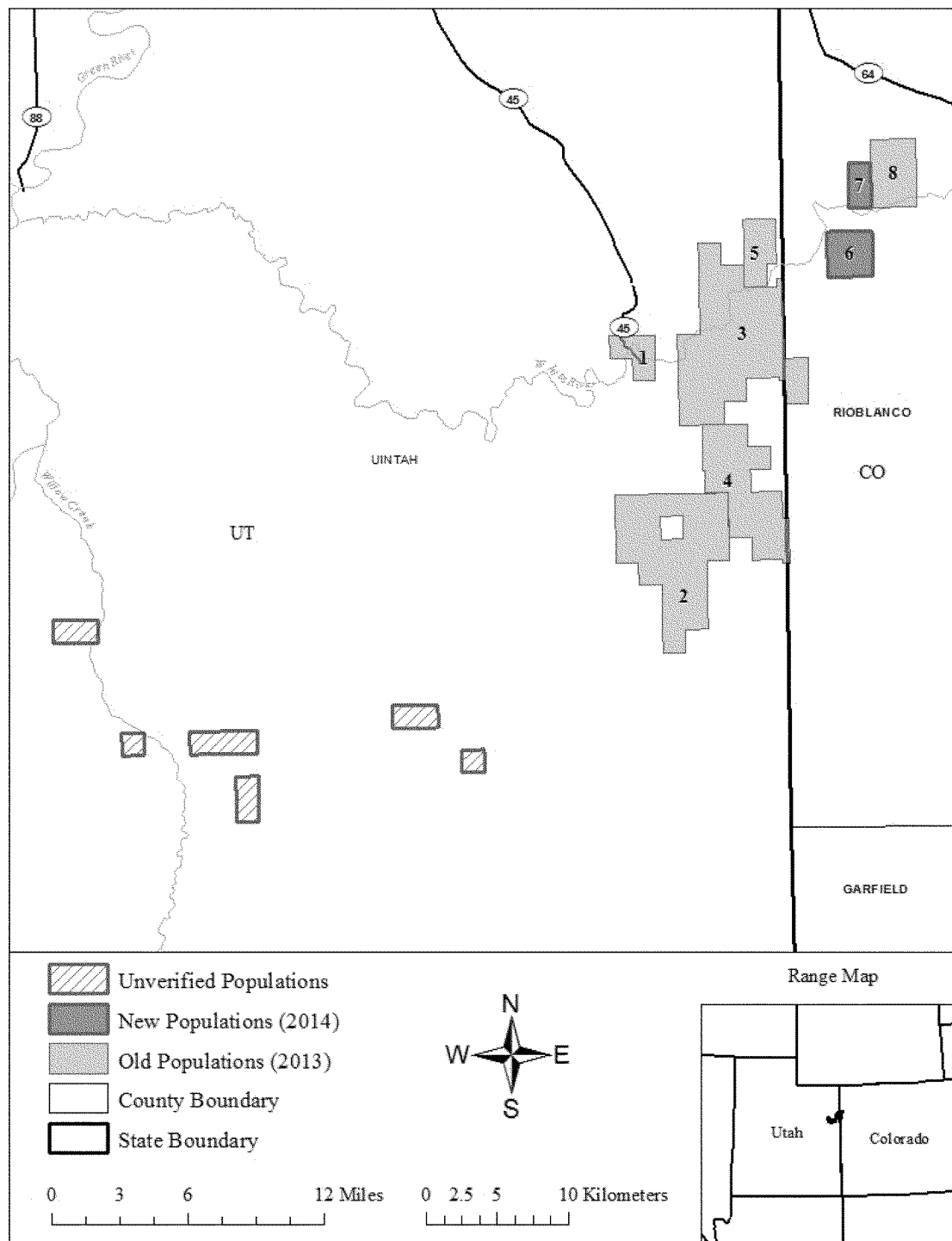
White River beardtongue was first described as a new species, *Penstemon albifluvis*, in 1982 (England 1982, entire). In 1984, the taxon was described as variety *P. scariosus* var. *albifluvis* (Cronquist *et al.* 1984, p. 442). *P. s.* var. *albifluvis* has a shorter corolla and shorter anther hairs than typical *P. scariosus*. White River beardtongue is also unique from *P. scariosus* because it is endemic to low-elevation oil shale barrens near the White River along the Utah–Colorado border (see Habitat below for more information), while typical *P. scariosus* habitat occurs at higher elevations on the West Tavaputs and Wasatch Plateaus of central Utah (Cronquist *et al.* 1984, p. 442).

Distribution and Trends

The historical range of White River beardtongue has likely not changed since the species was first described in 1982 (England 1982, pp. 367–368). White River beardtongue was first discovered along the north bank of the White River 1 mile upstream from the Ignacio Bridge (England 1982, p. 367). The historical range was described as occurring from east central Uintah County, Utah, to Rio Blanco County, Colorado (England 1982, p. 367).

White River beardtongue's current range extends from Raven Ridge west of Rangely in Rio Blanco County, Colorado, to the vicinity of Willow Creek in Uintah County, Utah. The bulk of the species' range occurs between Raven Ridge and Evacuation Creek in eastern Utah, a distance of about 30 km (20 mi).

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(Figure 2) (CNHP 2012, entire; UNHP 2012, entire). Herbarium collections from 1977 to 1998 indicate that the species' range might extend further west to Willow Creek, Buck Canyon, and Kings Well Road (UNHP 2012, entire).

However, we have not revisited the herbarium collection locations to confirm the species' presence—it is possible that the herbarium collections represent individuals of the closely related and nearly indistinguishable

Garrett's beardtongue (*Penstemon scariousus* var. *garettii*). Therefore, we consider these to be unverified locations and excluded these records from further analysis (Figure 2).

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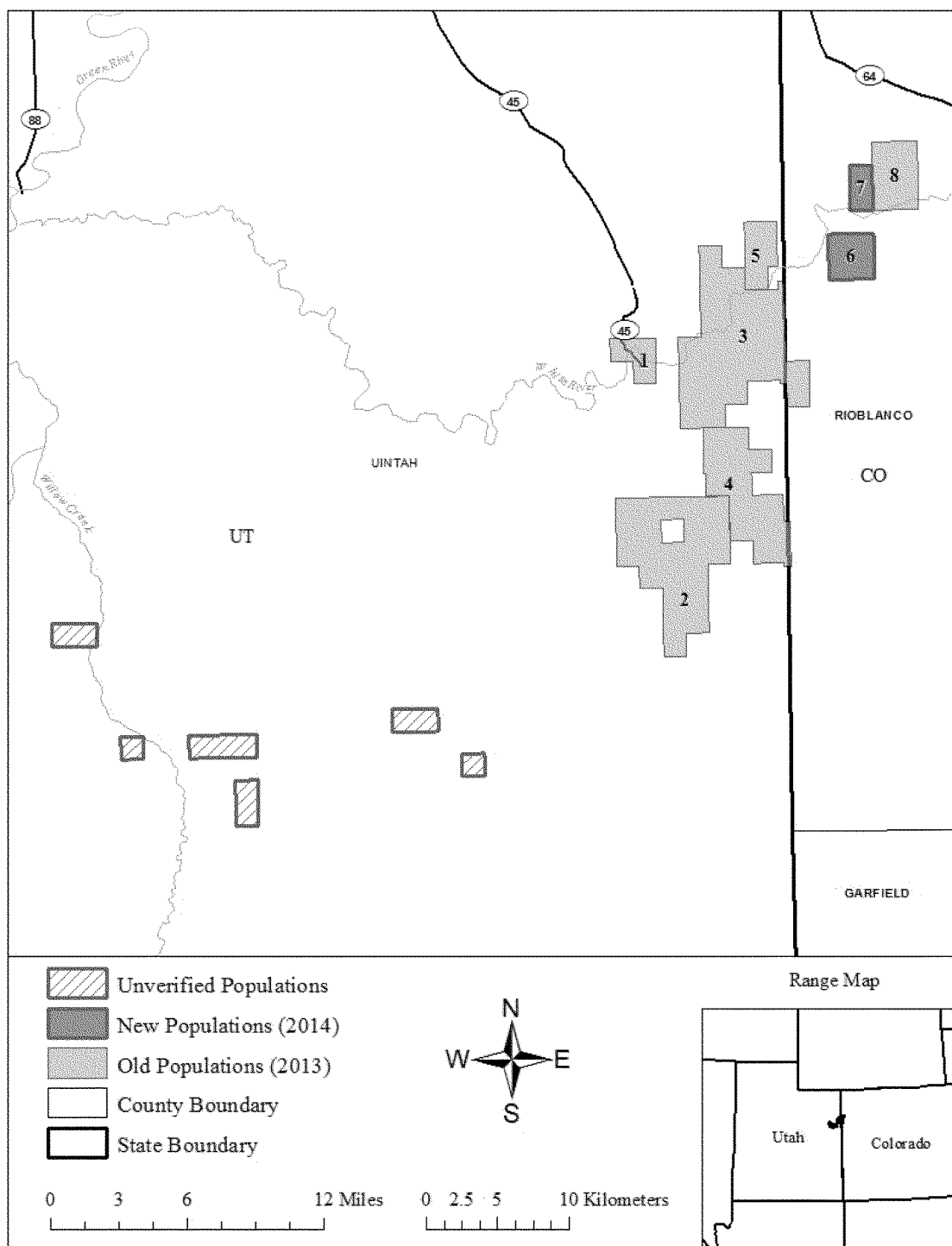


Figure 2. White River beardtongue's range.

We do not have complete surveys for White River beardtongue and thus do not know the total population size for this species. Our best population estimate is 12,215 individuals (including 792 new plants that were found during surveys in 2013) (Service 2014b).

In our 2013 proposed rule, we delineated seven populations in the main portion of White River beardtongue's range using data collected through 2012. Based on new 2013 survey information, we have now reanalyzed the data using the methodology explained above under

Graham's beardtongue—Species Information. We now know of 8 populations; 5 populations in Utah and 3 populations in Colorado (Figure 2). Approximately 61 percent of the known population of White River beardtongue occurs on BLM land, with the remainder

occurring on State and private lands
(Table 2).

TABLE 2—NUMBER OF KNOWN INDIVIDUALS OF WHITE RIVER BEARDTONGUE BY LANDOWNER

[* Data as Presented in the 2013 Proposed Rule Includes Surveys Through 2012; ** Data as Presented in This 2014 Final Rule Includes Surveys Through 2013.]

	Number of individuals (2013 pro- posed rule) *	Percent of total in (2013 pro- posed rule) *	Number of individuals (2014) **	Percent of total in (2014) **
Federal	7,054	62	7,481	61.2
Private	3,093	27	3,458	28.3
State	1,276	11	1,276	10.5
Tribal	0	0	0	0
Total	11,423	100	12,215	100

All of our long-term monitoring information for the species comes from two sites that were monitored from 2004 to 2012 (populations 1 and 6, see Figure 2), and one site that was monitored from 2010 to 2012 (population 3, see Figure 2). At one site, plants declined over this time and the other two sites increased slightly (McCaffery 2013a, p. 8). Although two of three sites were found to be stable, we do not know if this finding represents the trend for all populations of the species across its range, but it represents the best available information on population trends for the species.

White River beardtongue flowers each year regardless of new seedling recruitment, in contrast to Graham's beardtongue (McCaffery 2013a, p. 9). Like Graham's beardtongue, White River beardtongue is vulnerable to stochastic events as well as increases in stressors or declining habitat conditions (McCaffery 2013a, p. 19). Also like Graham's beardtongue, no link was found between reproduction and precipitation on a regional level (McCaffery 2013a, p. 16), but this issue should be studied on a more local scale. In 2009, a significant recruitment event occurred in two of the study populations (Dodge and Yates 2010, pp. 11–12). Many of these seedlings died between 2009 and 2010, but the net result was an increase in population size by the end of the study (Dodge and Yates 2011, pp. 6, 10). Continued monitoring is necessary to determine the frequency of recruitment and how this influences the long-term population trends of this species. In addition, like Graham's beardtongue, we need further studies to determine what factors are driving population dynamics of White River beardtongue.

Habitat

White River beardtongue is restricted to calcareous (containing calcium

carbonate) soils derived from oil shale barrens of the Green River Formation in the Uinta Basin of northeastern Utah and adjacent Colorado. The species overlaps with Graham's beardtongue at sites in the eastern portion of Graham's beardtongue's range.

White River beardtongue is associated with the Mahogany ledge and Parachute Creek formation. The habitat of White River beardtongue is a series of knolls and slopes of raw oil shale derived from the Green River geologic formation (Franklin 1995, p. 5). These soils are often white or infrequently red, fine-textured, shallow, and usually mixed with fragmented shale. These very dry substrates occur in lower elevations of the Uinta Basin, between 1,500 and 2,040 m (5,000 and 6,700 ft), and the species occurs at an average elevation of 1,847 m (6,060 ft). About one-fifth of all known point locations of White River beardtongue are on slopes of 10 degrees or less, with an average slope for all known points of 19.2 degrees (Service 2013, pp. 3–4). White River beardtongue individuals usually grow on southwest-facing exposures (Service 2013, p. 1).

Species growing with White River beardtongue include saline wildrye, mountain thistle, spiny greasewood, Utah juniper, two-needle piñon, and shadscale saltbush (UNHP 2013, entire), and many oil shale endemic plant species (Neese and Smith 1982, p. 58; Goodrich and Neese 1986, p. 283). Other beardtongue species growing in the vicinity of White River beardtongue include thickleaf beardtongue and Fremont's beardtongue (Fitts and Fitts 2008, pp. 13–28; Fitts and Fitts 2009, pp. 11–26; Fitts 2010, pp. 15–21; Fitts 2014, pers.comm.) and these are likely important for supporting pollinators.

Biology

White River beardtongue is long-lived due to the presence of a substantial and multi-branched woody stem (Lewinsohn

2005, p. 3), and individual plants can live for 30 years (Service 2012c, p. 3). Most plants begin to flower when the woody stem reaches 3 to 4 cm (1 to 1.5 in.) in height (Lewinsohn and Tepedino 2005, p. 4), usually in May and June.

The species is pollinated by a wasp, *Pseudomasaris vespoides*, and several native, solitary bee species in the genera *Osmia*, *Ceratina*, *Anthophora*, *Lasioglossum*, *Dialictus*, and *Halictus* (Sibul and Yates 2006, p. 14; Lewinsohn and Tepedino 2007, p. 235). These pollinators are medium in size compared to the larger pollinators generally associated with Graham's beardtongue (see Background—Graham's beardtongue, Biology, above). White River beardtongue has a mixed mating system, meaning it can self-fertilize but produces more seed when it is cross-pollinated (Lewinsohn and Tepedino 2007, p. 234). Thus, pollinators are important for maximum seed and fruit production.

Based on their medium size, the pollinators of White River beardtongue are capable of travelling and moving pollen across at least 500-m (1,640-ft) distances (Service 2012b, pp. 8, 13). Although White River beardtongue has low flower visitation rates by pollinators, there is no evidence that pollinators are limiting for this species (Lewinsohn and Tepedino 2007, p. 235). It is important to maintain the diversity of pollinators by maintaining vegetation diversity for White River beardtongue because it stabilizes the effects of fluctuations in pollinator populations (Lewinsohn and Tepedino 2007, p. 236).

We have very little information regarding the genetic diversity of White River beardtongue. This species, like Graham's beardtongue, is likely not as genetically diverse as other common, sympatric beardtongues (Arft 2002, p. 5).

Summary of Comments and Recommendations

In the proposed rules published on August 6, 2013 (78 FR 47590), we requested that all interested parties submit written comments on the proposals by October 7, 2013. We also contacted appropriate Federal and State agencies, scientific experts and organizations, and other interested parties and invited them to comment on the proposals. Newspaper notices inviting general public comment and announcing our informational meeting and public hearing were published in the Salt Lake Tribune, Deseret News, and Uintah Basin Standard. We received requests for a public hearing, which was held in Vernal, Utah, on May 28, 2014. We reopened the comment period on May 6, 2014, for 60 days (79 FR 25806), to accept comments on the proposed rules and several related documents (see Previous Federal Actions).

During the 2 comment periods for the proposed rules, we received 4,889 comment letters supporting or opposing the proposed listing of Graham's and White river beardtongues with designated critical habitat. During the May 28, 2014, public hearing, one organization commented on the proposed rules. All substantive information provided during the comment periods is either incorporated directly into this document or addressed below.

In accordance with our peer review policy published on July 1, 1994 (59 FR 34270), we solicited expert opinion from seven appropriate and independent specialists with scientific expertise that included familiarity with Graham's and White River beardtongues and their habitat, biological needs, and threats. We received responses from four of the peer reviewers. We reviewed all comments received from the peer reviewers for substantive issues and new information regarding the listing of Graham's and White River beardtongues. One peer reviewer said that our description and analysis of the biology, habitat, geology, soils, plant community associates, climatic conditions, population trends, and historic and current distribution of the species are accurate. Two peer reviewers found that the proposed rule provided an accurate and adequate review and analysis of the factors affecting the species. Two peer reviewers also stated that we reached logical conclusions and included pertinent literature. Other peer reviewer comments are addressed in the following summary and incorporated

into this withdrawal document as appropriate.

We also received and considered many comments relating to critical habitat and the associated environmental assessment and economic analysis of critical habitat, but responses to these comments are not included here because we are withdrawing the proposed listing and critical habitat rules for the Graham's beardtongue and White River beardtongue. Where comments on our proposed critical habitat are also relevant to the species' biology or distribution, or relevant to our withdrawal decision, we have addressed these issues in this document as appropriate.

Peer Review Comments

Comment (1): One peer reviewer urged us to protect Graham's and White River beardtongues by designating an Area of Critical Environmental Concern (ACEC).

Our Response: An Area of Critical Environmental Concern may only be designated by the BLM. An ACEC that overlaps a portion of Graham's and White River beardtongues has been designated in Colorado by the BLM. No ACEC was designated by BLM in Utah.

Comment (2): Several peer reviewers provided corrections, clarifications, or suggested additions to the biological background information for Graham's beardtongue. One peer reviewer clarified that a cool, wet spring may have reduced herbivory on Graham's beardtongue, but effects on reproduction are not definitive. One peer reviewer pointed out that the flowering period is late April to late June with seeds ripening between mid-June and mid-August. One peer reviewer suggested that we add that, "maintaining both a sufficient number of reproducing plants per population, a sufficient number of those populations and connectivity between those populations is needed to ensure cross-pollination and genetic diversity of the species." Two peer reviewers suggested that we change our description of the average lifespan of the species—the average lifespan is unknown, but plants have been documented surviving for at least 10 years in monitoring plots over a 10-year period.

Our Response: We included this information under Background—Graham's beardtongue, *Species Information*.

Comment (3): One peer reviewer stated that sheep grazing can have significant impacts to Graham's beardtongue. Sheep were observed browsing all inflorescences of Graham's

beardtongue from one monitoring plot eliminating all reproduction at the site for the year.

Our Response: We included this observation under Summary of Factors Affecting the Species, Grazing and Trampling. In our proposal and this document we acknowledge that herbivory and trampling can be severe at some locations, but despite such intense impacts from sheep, this monitoring site still had a stochastic population growth rate slightly above one (MacCaffrey 2013a, p. 15); therefore, we do not consider grazing to be a threat to the species.

Comment (4): One peer reviewer provided updated information about the results of transplantation of Graham's beardtongue in 2012. None of the plants survived transplantation.

Our Response: We included this additional information under Summary of Factors Affecting the Species, Road Maintenance and Construction.

Comment (5): One peer reviewer asked us to update our citation of Dodge 2013 to Reisor 2013, because the author's name has changed.

Our Response: We did not cite this document correctly in the 2013 proposal, so we have updated this citation.

Comment (6): One peer reviewer found that our description of the slopes where the species are found was accurate but may represent a survey bias because some slopes are too steep to safely survey, so the proportion of plants on steeper slopes may be higher than we represent.

Our Response: We agree with the comment, but our analysis of the relationship between slopes and species' presence is based on best available information, which shows that the average slope where the species occurs is 17.6 degrees. Since there are little data showing that the species occurs on steeper slopes, we used the best information available.

Comment (7): One peer reviewer questioned the importance of "cushion-like" herbs we described in our proposed critical habitat rule (78 FR 47832) to the natural community where Graham's and White River beardtongue grows and wondered what other cushion-like plants besides *Arenaria hookeri* occur in the same natural community.

Our Response: Cushion-like plants in Graham's beardtongue habitat include *Chamaechaenactis scaposa* (fullstem), *Parthenium ligulatum* (Colorado feverfew), *Townsendia mensana* (table townsend daisy), the *Hymenoxys* species (rubberweeds) and some of the

Cryptantha species (*Cryptantha*) (Neese and Smith 1982).

Comment (8): One peer reviewer said that Graham's beardtongue overlaps the Douglas Creek and Parachute Creek members of the Green River Formation but agreed that the description of the soils and geology of White River beardtongue in our proposed rule to designate critical habitat (78 FR 47832) was accurate.

Our Response: We found that 2,654 Graham's beardtongue plants overlap with the Douglas Creek member of the Green River formation, which represents a small percentage of the total population. We have updated the Background—Graham's beardtongue, *Species Information*, Habitat section to reflect this overlap.

Comment (9): One peer reviewer noted that photographs show Graham's beardtongue growing on open slopes, canyon rims, and occasionally in pinon-juniper openings.

Our Response: We include these habitat types in this document (see Background—Graham's beardtongue, *Species Information*, Habitat).

Comment (10): One peer reviewer noted the importance of pollinators. They cited an example of a plant species that lost its pollinator and stopped producing seed.

Our Response: We agree with the importance of pollinators and retain this discussion in our withdrawal.

Comment (11): One peer reviewer found that our description of the importance of intact soils to Graham's and White River beardtongues is correct although he described finding Graham's and White River beardtongues in disturbed soils adjacent to a pipeline and road.

Our Response: We are aware of isolated instances where the species may persist adjacent to soil disturbance. However, these locations do not provide the full complement of associated plants or pollinator species and thus would not provide suitable habitat for the species' long-term viability.

Comment (12): One commenter provided information that thistle beardtongue and Fremont's beardtongue occur in the vicinity of Graham's and White River beardtongue and might be important for supporting pollinators.

Our Response: We agree with the comment and included this information in our description of the habitat (see Background—Graham's beardtongue and White River beardtongue, *Species Information*, Habitat).

Comment (13): One peer reviewer asked us to add the citation of Dodge and Yates 2009 to support our discussion that the highest number of

fruits is produced when flowers are cross-pollinated.

Our Response: We reviewed the Dodge and Yates 2009 paper and have included the citation under Summary of Factors Affecting the Species, Road Construction and Maintenance and Small Population Size.

Comment (14): One peer reviewer informed us that additional occurrences of Graham's beardtongue were found in 2013.

Our Response: We have incorporated the additional data from the 2013 survey season into our analysis.

Comment (15): One peer reviewer suggested that we review herbarium specimens to verify the range of White River beardtongue.

Our Response: The peer reviewer did not provide any additional information or documentation that verifies the correct identification of herbarium specimens or the accuracy of locations where the herbarium specimens were found. Until both of these are verified by a qualified botanist, we will continue to consider these herbarium specimens as unverified. We identified the range of White River beardtongue by using the best available information, which consists of locations that were verified both to the correct subspecies and location. This documented information came from many sources including the UNHP (2012 and 2013b), CNHP (2014), BLM (2013b) and private parties (see Background—White River Beardtongue, *Species Information*, Distribution and Trends). We will consider additional information as it becomes available.

Comment (16): One peer reviewer stated that he has observed deer grazing on Graham's beardtongue.

Our Response: Deer are listed as one of the grazers of Graham's beardtongue under Summary of Factors Affecting the Species, Grazing and Trampling. However, we do not have information suggesting that deer herbivory is a threat to the species. As discussed in the section listed above, we do not consider grazing by deer a threat to the species because demographic data show the monitoring sites for Graham's beardtongue are stable despite the current level of observed herbivory (MacCaffrey 2013a, p. 15).

Comment (17): While building a species' distribution model for Graham's beardtongue, one peer reviewer found that late-season moisture was important in determining the distribution of the species.

Our Response: We requested more information on this topic, but the peer reviewer did not provide data that supports this assumption, and we do not have additional information. We do

not fully understand the relationship between the precipitation regime and the response of Graham's beardtongue. We welcome any further information on this relationship.

Comment (18): One peer reviewer noted that surveys for the Graham's and White River beardtongues were also conducted by the Utah Natural Heritage Program and funded by the Utah Endangered Species Mitigation Fund and Uintah County.

Our Response: We recognize and are appreciative of the contributions to surveying for both beardtongue species by the State of Utah and Uintah County. We explain the role of the State and County under Background—Graham's beardtongue, *Previous Federal Action*. These surveys have contributed to our improved understanding of the distribution of both species.

Comment (19): One peer reviewer believed that our plant data were inadequate to determine population abundances and trends because we analyzed the population data as a whole instead of analyzing the data separately for each individual population. Further, the peer reviewer stated that metapopulation dynamics are important for understanding population trends and that we should evaluate these relationships.

Our Response: This document discusses the available monitoring information, our assumptions, and the lack of abundance data (see Background—Graham's beardtongue, *Species Information*, Distribution and Background—White River beardtongue, *Species Information*, Distribution). We did not lump species data to determine trends but instead used the best available information on population trends, which comes from two sites for each species. We recognize that individual population trends for other populations may differ from the monitored populations, and to that end two new monitoring sites were added for Graham's beardtongue in 2010, and one additional monitoring site was added in 2010 for White River beardtongue. In addition, rangewide monitoring will be initiated under the 2014 Conservation Agreement. The two sites that were monitored for 9 years show that those individual populations of Graham's beardtongue were stable and that the two monitored populations of White River beardtongue were stable and close to stable. Further work is needed to determine if the trends at these sites are representative of the entire population.

We acknowledge that there are gaps in our understanding of the species' abundance based on the available

abundance data. We reported only known abundances in the proposed rule and in this document, and acknowledge that the actual abundance of both species may be higher.

Comment (20): One peer reviewer identified an additional population of White River beardtongue that was located in Colorado in 2013.

Our Response: We have included the additional population of White River beardtongue found in Colorado into our dataset (see Figure 2).

Comment (21): One peer reviewer asserted that we did not support our conclusions regarding the historical distribution and abundance of the Graham's and White River beardtongues, as grazing may have extirpated additional populations of both species. Widespread, heavy, and unregulated historical grazing may have reduced the distribution and abundance of the species. More recently, livestock grazing was reported as a threat to Graham's beardtongue by several biologists (Neese 1982; Frates 2014).

Our Response: The historical distribution and abundance of Graham's beardtongue is unknown, and the reviewer did not provide information on the potential extent of the historical range. Historical heavy grazing and trampling may have extirpated some individuals or populations of both species; however, this most likely did not reduce the range of either species because current monitored populations are still stable or close to stable despite observations of livestock grazing and trampling at monitoring sites.

Comment (22): One peer reviewer found that we did not sufficiently analyze the naturalness of the hydrologic regime as a factor affecting the species.

Our Response: We agree that the hydrologic regime may be important for these beardtongues, especially since subsurface mining may produce fissures that alter surface hydrologic regimes (Hotchkiss *et al.* 1980, p. 46). We do not have nor did the peer reviewer provide specific information on the hydrologic regime for these species. However, because both plant species occur across a wide range and in sufficient numbers, we find that the current hydrologic regime is sufficient to sustain the species for the future with the establishment of conservation areas.

Comment (23): One peer reviewer suggested that we consider livestock trampling as a significant threat because it can affect the species at multiple scales including direct impacts to the species, degradation of habitat, and even large landscape effects to the

community including pollinators, soils, and hydrology.

Our Response: We do not fully understand how Graham's and White River beardtongues respond to livestock grazing pressure, including trampling. However, monitored populations that overlap active grazing allotments show a stable trend over a 9-year monitoring period. Therefore, we did not find livestock trampling to be a threat, as discussed under Summary of Factors Affecting the Species, Grazing and Trampling.

Comment (24): One peer reviewer found that we did not sufficiently consider small population size as a factor affecting the species, citing that small populations are more likely to go extinct than large populations, and that isolated small populations become even more vulnerable to extinction.

Our Response: Although we found that small population size contributed to other factors that were a cumulative threat to the species without protections, we no longer consider small population size a threat to the species because we have reduced threats that may isolate populations through the conservation measures in the 2014 CA. Sufficient numbers of large and small populations of both beardtongue species will be conserved to provide resiliency and redundancy to each species throughout their ranges. The 2014 CA provides for the establishment of conservation areas that protect these populations and provide connectivity. The protection of populations within conservation areas will provide for the continued persistence of both species.

Comment (25): One peer reviewer noted that during surveys in 2013 an extensive and moderately dense cover of purple mustard (*Chorispora tenella*), an invasive weed, was found occurring with Graham's beardtongue in the Raven Ridge ACEC. This reviewer concluded that weed invasion is a threat to Graham's beardtongue.

Our Response: We have updated the Summary of Factors Affecting the Species, Invasive Weeds section of this document with this new information. However, we do not agree that this instance of an invasive weed invasion constitutes a threat to the species because there are sufficient numbers of populations of Graham's beardtongue that are unaffected by invasive weeds. In addition, further evidence that purple mustard is negatively impacting the population of Graham's beardtongue would be needed for it to be considered a threat to the species.

Comment (26): One peer reviewer agreed with our conclusion that both Graham's and White River beardtongues

meet the definition of a threatened species and that they should be protected under the Act.

Our Response: At the time of publication of the 2013 proposed listing rule, we concluded that threats to Graham's and White River beardtongues included negative effects from energy exploration and development and cumulative impacts from increased energy development, livestock grazing, invasive weeds, small population sizes, and climate change. These threats have since been addressed in the 2014 CA, in part by creating conservation areas that will protect the species from ground-disturbing activities.

Tribal Comments

(27) Comment: The Ute Indian Tribe (Tribe) asked us to comply with our treaty and trust responsibilities to the Tribe, the Executive Order on Government-to-Government Consultation, the Department of the Interior's Policy on Consultation with Indian Tribal Governments, and the Secretarial Order on American Indian Tribal Rights, Federal—Tribal Trust Responsibilities, and the Act. The Tribe stated that listing actions will directly affect the Tribe and that proposed critical habitat borders trust lands and are within the Tribe's Uintah and Ouray Reservation. Since the Tribe is a major energy producer, they are concerned that the proposed actions will affect the economy and interests of the Tribe by significantly impacting oil and gas development on their Reservation.

Our Response: In the proposed rule, we determined that no tribal lands were known to be occupied by the beardtongues. Therefore, we did not propose to designate critical habitat for either species on tribal lands. It is possible that one or both species occurs on tribal lands in potential habitat that has not been surveyed. At the time of publication of our May 6, 2014, document reopening the comment period (79 FR 25806), we contacted the Tribal chair and Tribal attorney by phone and email regarding the proposed rules and the document, and updated them on the reopening of the public comment period and the availability of the draft 2014 CA, economic analysis, and environmental assessment for review and comment. Also, at that time we offered to discuss the proposed rules with the Tribe.

State and County Comments

(28) Comment: The Utah Governor's Office, Utah Public Lands Policy Coordination Office (PLPCO), Duchesne County, Carbon County, and other commenters stated that the listing of

Graham's and White River beartongues should be withdrawn because there is no basis for concluding that either species is threatened as defined in the Act. The State finds the proposal to list is unsupported by sufficient scientific information, data, and analysis and is based on inaccurate interpretations concerning regulatory actions such as energy development and mining proposals. Additionally, the State has expertise in the conservation of species and in the responsible development of oil shale and oil and gas resources. Such expertise must be considered in the evaluation of data, the regulatory mechanisms available, and in the ability to generate and enforce a conservation agreement for both beartongues.

Our Response: We used the best scientific and commercial information available for the purpose of making a final listing determination for Graham's and White River beartongues, including the newly created 2014 CA, and we concluded that the species no longer meet the definitions of threatened or endangered species under the Act. We agree that Graham's and White River beartongue conservation can be accomplished through the 2014 CA (see Ongoing and Future Conservation Efforts).

(29) Comment: The PLPCO and several commenters stated impacts to the species from oil shale and traditional oil and gas development in the future will be limited. The PLPCO cites a University of Utah study (2013) to support the growth projections of the industry, and concluded that development would remain minimal due to low natural gas prices; however, the study did not specify a timeframe for this projection. Even if development were to occur, the commenters believe we overstated its impact. Any projected drilling in beartongue habitat will be for natural gas rather than oil. The PLPCO and another commenter stated promising new production techniques for oil shale and tar sands will likely further reduce forecasted environmental impacts. Other commenters cited economic and technical uncertainties that call into question large-scale, rapid oil shale development on public and private lands.

Our Response: We used the best scientific and commercially available information for our analysis. Our analysis of energy development included the locations of traditional hydrocarbon resource deposits and oil shale and tar sands resources, plant abundance and habitat overlapping these areas, and the regulatory mechanisms in place to protect the beartongues in these areas. While a

high level of development within these species' habitats is not yet realized, we expect it to increase in the future, although we acknowledge some uncertainties regarding when oil shale and tar sands development will occur. A number of factors may limit the growth rate of the oil shale and traditional oil and gas industry, but these factors do not remove the likelihood of energy development in the future. We included the University of Utah (Institute for Clean and Secure Energy 2013, entire) study projections of likely industrial growth in our discussion of oil shale and tar sands in this document (see Summary of Factors Affecting the Species, Energy Exploration and Development). However, the 2014 CA provides significant conservation actions for the beartongues on State, private, and Federal lands across their range (see Ongoing and Future Conservation Efforts). We determined that the conservation agreement measures will be effective at reducing threats to the beartongues.

(30) Comment: The PLPCO, Duchesne County, and other commenters stated that we made erroneous factual assumptions about likely energy development on BLM lands and its impact on the beartongues. The commenters stated that the BLM determined no commercially viable technologies for oil shale extraction in Utah exist, and that BLM lands will not be available to leasing except in 160-acre increments under research, development, and demonstration (RD&D) leases. Only upon compliance with lease provisions would additional lands become available for commercial lease. Currently, there is only one active RD&D lease in Utah. Another commenter stated there are no actual proposals to develop oil shale from the vast majority of these parcels. Another commenter stated the Consolidated Appropriations Act of 2008 placed a Congressional moratorium on all Federal oil shale leasing.

Our Response: The BLM lands identified in the proposed rule and this withdrawal are based upon acreages potentially available for leasing as identified in the BLM Programmatic Oil Shale and Tar Sands Environmental Impact Statement (OSTEIS). While a high level of development within these species' habitats is not yet realized, we expect it to increase in the future because the Energy Policy Act of 2005 identifies the entire range of the beartongues as a priority for oil shale and tar sands development, requires the establishment of a commercial leasing program, and increases the lease acreage

restriction to 50,000 acres per individual or corporation. While the growth of the industry may be slow, this does not remove the likelihood of the threat from energy development in beartongue habitat where energy resources exist. The Consolidated Appropriations Act of 2008 did not place a moratorium on oil shale leasing; however, it did specify that oil shale regulation development and leasing was not funded that year. However, the 2014 CA reduces the threat to Graham's and White River beartongues on BLM lands by establishing conservation areas where surface disturbance will be limited, and where plants will be buffered from surface disturbances by distances of 91.4 m (300 ft). Outside conservation areas on BLM lands, any surface disturbance will avoid plants by 91.4 m (300 ft). These measures sufficiently address the threats to both species from oil shale development.

(31) Comment: The PLPCO and other commenters believe we overstated impacts from potential oil shale development on State and private lands. The commenters stated that these projects are designed to minimize surface impacts and impairment of plant species and thus would limit disturbance to only a few thousand acres maximum at any one time. Additionally, the projects will transition from surface mining to underground mining depending upon the depth of the resource. Another commenter stated that the economic reality is that surface mining would not occur in areas with an average overburden greater than 30.5 m (100 ft), and the most commercially attractive areas for oil shale mining would be candidates for underground mining. Commenters further stated that the land occupied by surface mining at any one time would be a small fraction of the habitat area, and mining areas would be rapidly reclaimed.

Our Response: In our 2013 proposal, we assumed surface mining would occur where the overburden is less than 152 m (500 ft) deep. This is consistent with the Record of Decision for the OSTEIS, which stated surface mining of oil shale in Utah is allowed where the overburden is 0 to 500 ft thick. While a high level of development within these species' habitats is not yet realized, we expect it to increase in the future because the Record of Decision for the OSTEIS identifies a large percentage of the range of the beartongues for oil shale and tar sands development. In addition, we do not have documentation that reclaimed mined areas can support either beartongue species. However, the 2014 CA provides significant conservation

actions for both beardtongues on State, private, and Federal lands across their ranges (see Ongoing and Future Conservation Efforts). We determined that the 2014 CA measures will reduce threats to the beardtongues.

(32) Comment: The PLPCO and one other commenter stated we incorrectly indicated that no regulatory mechanisms exist with regard to Red Leaf's project on SITLA lands. The State permit for Red Leaf's project specifically includes protection for Graham's beardtongue.

Our Response: We appreciate the information regarding the permit for the Red Leaf project. Although the permit may provide some conservation benefits, we also note that Red Leaf's mining permit allows that most of the land surface will be disturbed by mining. Therefore, the long-term effectiveness of the measures described in the permit is uncertain. Although the 2014 CA does not provide protections for Graham's beardtongue on the property leased by Red Leaf, a sufficient number of plants are protected by the 2014 CA on BLM lands within that same population.

(33) Comment: The PLPCO and one other commenter concluded that we grossly overstated the footprint of the Enefit project and the number of plants contained therein by failing to use accurate mine plan data that are publicly available. Commenters stated that surveys in 2013 of the Enefit South Project found 117 and 413 individuals of Graham's and White River beardtongue, respectively. These numbers represent 0.3 percent and 3 percent of known Graham's and White River beardtongue plants, respectively, rangewide rather than the 19 percent and 26 percent identified in the proposed rule. Enefit stated that their South Project will develop 2,833 ha to 3,642 ha (7,000 to 9,000 ac) rather than the 10,117 ha (25,000 ac) identified in the proposed rule.

Our Response: We used the best scientific and commercially available information for our analysis. Our analysis of the Enefit project was based upon total acreage that was either owned, leased, or optioned for lease by the company; the amount of plant abundance and habitat overlapping these areas; and the regulatory mechanisms to protect the beardtongues on these areas. We updated the information in this document to differentiate impacts from Enefit's South Project from the entire area owned, leased or optioned for lease by Enefit (see Summary of Factors Affecting the Species, Energy Exploration and Development).

(34) Comment: Several commenters stated there are sufficient regulatory mechanisms on BLM lands to protect the beardtongues, including protections through the OSTEIS and those applied as a BLM special status species. The PLPCO and SITLA stated that we provide no support for why we believe spatial buffers are not sufficient to minimize impacts to the beardtongues. Another commenter stated the BLM Vernal Field Office Resource Management Plan (RMP) creates a setback zone from the Mahogany Ledge outcrop so this area believed to be of greatest concern is not available for leasing. The commenter stated that Graham's beardtongue survival can be adequately ensured through avoidance and revegetation. Another commenter and Duchesne County stated the Raven Ridge ACEC protects 87 percent of all known Graham's beardtongue plants in Colorado and is sufficient to protect the species. In the ACEC, motorized travel is restricted to existing roads and there is no surface occupancy restriction for new oil and gas leases. Additionally, commenters stated that we discounted existing efforts to protect the species by energy companies. Another commenter stated the majority of oil shale resources and the majority of known plants are on Federal land and thus the Federal leasing restrictions and imposed plant protections will be inherently limiting and protective.

Our Response: The protections in the OSTEIS apply only to plant species listed under the Act. The Vernal RMP does not create a setback zone from the Mahogany Ledge outcrop. However, landscape-level protections are included in the 2014 CA through the identification of conservation areas for the species rangewide (see Ongoing and Future Conservation Efforts) and by the Raven Ridge ACEC protections in Colorado.

(35) Comment: The PLPCO stated that, since the oil shale industry will develop gradually, we should consider a research program to determine the beardtongues' ability to be propagated and moved into reclaimed areas. Another commenter stated the beardtongues are robust and would likely succeed in reseeded or transplanting efforts on reclaimed soils.

Our Response: We agree that additional research on this topic would be beneficial because restoration of plants of arid ecosystems remains largely unsuccessful and unproven. Additional studies are being planned through the 2014 CA to better assess the ability of the beardtongue species to establish and persist on disturbed or

reclaimed soils (see Ongoing and Future Conservation Efforts).

(36) Comment: The PLPCO and SITLA stated that we failed to show that pristine, natural environments are necessary for the species' conservation, and it is speculative to conclude disturbance is detrimental to these species.

Our Response: Although individual plants may occupy some disturbed habitats, it is unlikely that these disturbed areas can support the species on an ecosystem level and support viable populations for the long-term. With very few exceptions, all sites where both beardtongue species occur are located in undisturbed soils. Additional studies are planned through the 2014 CA to better assess the ability of the beardtongue species to establish and persist on disturbed or reclaimed soils (see Ongoing and Future Conservation Efforts).

(37) Comment: The PLPCO, SITLA, and another commenter stated that our evidence for indirect effects and habitat fragmentation effects on the beardtongues is speculative. One commenter stated that there is no clear evidence the environment is as fragmented as is implied. They stated that Graham's beardtongue colonies are already widely dispersed, which implies the species tolerates a high degree of fragmentation.

Our Response: We used information on the effects of habitat fragmentation on other similar plant species to infer what the effects would be to the beardtongues, because this represented the best available information. Some effects of habitat fragmentation include smaller and more isolated populations that have an increased risk of extinction, the potential for inbreeding depression, loss of genetic diversity, and lower sexual reproduction (see Summary of Factors Affecting the Species, Small Population Size). Although habitat fragmentation may not be currently high, we expect that, without the 2014 CA conservation actions, habitat fragmentation would increase in the future as large-scale surface mining and oil and gas development accelerates.

(38) Comment: The PLPCO, SITLA, and another commenter stated that we assume both species are tightly associated with the Mahogany Ledge within the Parachute Creek Member of the Green River formation, but plants occur far above and below this ledge and on various soil types.

Our Response: We acknowledge that not all individuals are found within the Mahogany Ledge feature. However, the majority of individuals, or approximately 63 percent and 69

percent of the total population of Graham's and White River beardtongues, respectively, are associated with the Mahogany Ledge feature.

(39) *Comment:* The PLPCO, SITLA, Duchesne County, and other commenters stated that we characterized the magnitude of the potential threats in terms of number of known populations or individuals while acknowledging the surveys for both species are incomplete. They further asserted that our understanding of the amount of potential habitat may be a substantial underestimation of the actual amount. Commenters stated that the predictive models for both species are pending and the model results will be based upon occurrences and data not considered in the proposed rule. One commenter stated that only a small portion of Graham's beardtongue habitat, perhaps less than 1 percent, across its range has been surveyed and thus it is fair to assume the species can be in areas that have not been surveyed. The commenter asserted that these errors and omissions emphasize our limited understanding of the species' distributions.

Our Response: We are required to use the best available information when evaluating a species' status and making a listing determination. We considered the predictive models during this analysis and agree there is additional potential habitat for both species. However, we based our determination on known information about the species, which includes survey data showing the extent and abundance of the species. Unsurveyed suitable habitat may increase both the known distribution and total population numbers for both species in the future.

(40) *Comment:* The PLPCO and SITLA questioned our methods to determine Element Occurrences (EOs) to delineate populations for the beardtongues when the pollinator travel distances differ from the EO delineation distance. The PLPCO stated the EO construct muddles a realistic discussion of the discontinuous distribution of the two species, does not allow the effects of activities to be weighed against actual plant locations, and thereby overstates the alleged fragmentation of habitat, establishes a completely false sense of accuracy, and does not use the best available data. Furthermore, commenters stated we do not provide information regarding the ecological significance of EOs, and PLPCO questioned why we did not use EOs in the threat analysis but rather individual plant numbers. The PLPCO urged us to

map the populations realistically for an accurate threat analysis.

Our Response: We used EOs to characterize the number of populations for the beardtongues because it is a standard protocol for delineating populations used by the State of Utah Heritage Program as well as other States' native plant programs (see Background—Graham's beardtongue, Distribution), and we find this an acceptable, biologically-based method to define populations. Much of the location data we received as point locations do not reflect the actual plant distribution across the landscape because in many cases one point represents many plants distributed over varying areas. Thus, we rely on EOs because of the discrepancy in the data and its standard use to delineate populations.

(41) *Comment:* The PLPCO and another commenter disagreed with our conclusion that the proposed Enefit oil shale project will reduce connectivity between Utah and Colorado Graham's beardtongue populations. They argue the current distance between populations 19 and 20 is 6.8 km (4.2 m), which is nearly 10 times the pollinator distance needed to maintain gene flow and connectivity between populations. The current pollinator distances of 700 m for Graham's beardtongue and 500 m for White River beardtongues are less than 6.8 km (4.2 m), so therefore any disturbance between these populations will not fragment populations that are not connected by pollinators.

Our Response: We can infer that gene flow must be occurring between these populations, because otherwise they would be different species, or diverging from the species. Graham's beardtongue pollinators are capable of travelling at least 700 meters (see Background—Graham's beardtongue, Biology) during foraging. However, pollinator dispersal distances can occur over a greater distance than foraging distance; dispersal distances for pollinator's of Graham's beardtongue pollinators are not known but long-distance dispersal is important for pollinators to ensure access to adequate resources (Tepedino 2014, entire). In addition, unsurveyed areas between populations 19 and 20 may contain occurrences of Graham's and White River beardtongue plants that are important for providing connectivity. We used genetic studies from other plant species, comprising the best information available, to infer the effects of habitat fragmentation on gene flow between beardtongue populations (see Small Population Size, below).

(42) *Comment:* The PLPCO disagreed with our conclusion that indirect factors

of pollinator limitation, dust, invasive weeds, grazing, small population size, and climate change pose a threat cumulatively. They contend that we have not demonstrated any impacts from any of these factors because neither species appears to suffer from pollinator limitations, dust, or invasive weeds.

Our Response: We stated in the 2013 proposed rule that the two beardtongues have stable populations and that substantial threats are currently not occurring. As such, we determined that livestock grazing, invasive weeds, small population sizes and climate change were not a threat in themselves, but when combined with energy development were a cumulative threat to the species. However, we concluded that barring additional conservation measures, threats would be likely to occur in the future, at a high intensity, and across both species' entire ranges. Our conclusions were based on future impacts to the species that would occur in concert with energy development. Furthermore, we discussed pollinator limitation as a negative effect of habitat fragmentation due to the threat of energy development.

(43) *Comment:* The PLPCO, SITLA, Duchesne County, and other commenters stated the proposed pollinator buffers are too large and not supported by science. They stated that we did not demonstrate that smaller pollination buffers would be insufficient.

Our Response: We used the best scientific and commercial information available to identify the pollinators of both beardtongues, identify the habitat requirements necessary to support these pollinators, and quantify their foraging distances to inform the pollinator buffer distance for both beardtongues (see Background—Graham's beardtongue, Biology, and Background—White River beardtongue, Biology).

(44) *Comment:* The PLPCO and SITLA stated the literature to support our assumption that pollinators will not cross roads or other disturbed areas is speculative. They stated that the pollinator studies cited have no relevance to species, ecological communities, or conditions in the Uinta Basin.

Our Response: We used the best scientific and commercial information available to identify the behavior of beardtongue pollinators in disturbed areas (see Summary of Factors Affecting the Species I. Energy Exploration and Development). The best available information includes studies from outside of the Uinta Basin that were

used to infer the effects to beardtongue pollinators.

(45) *Comment:* The PLPCO, SITLA and other commenters stated that we did not indicate whether the higher level of reproduction resulting from cross-pollination is necessary to maintain viable populations. They noted that our proposed rule concluded that low pollinator visitation for White River beardtongue was not considered a limiting factor.

Our Response: Cross-pollinated flowers produce more seeds and fruits than self-pollinated flowers in these species (Dodge and Yates 2009, p. 18; Lewinsohn and Tepedino 2007, p. 234). Since both beardtongues benefit from cross-pollination, it is important to maintain pollinator populations so that beardtongue seed production and genetic diversity are maximized. However, the establishment of conservation areas for both species will provide pollinator habitat and corridors between populations.

(46) *Comment:* The PLPCO and SITLA stated we did not indicate what “sufficiently large numbers or population distribution” means in the context of preventing inbreeding depression in Graham’s beardtongue.

Our Response: We assessed the effects from inbreeding depression based upon studies from other plant species because they comprised the best information available at the time. However, we did not attempt to apply the population size or distribution recommendations from these other studies to the beardtongues because those values are species specific. Therefore, we provided a general discussion regarding inbreeding depression. However, we do not believe that inbreeding depression is a threat because there are sufficient large populations of Graham’s beardtongue protected within conservation areas that allow for a large reservoir of genetic diversity.

(47) *Comment:* The PLPCO and SITLA and another commenter stated that we did not demonstrate that weeds are a threat or increase the risk of catastrophic wildfire. The PLPCO, SITLA, and another commenter stated the presence of weeds in adjacent habitat does not suggest they will encroach in actual beardtongue habitat. They further stated that weeds are unlikely to out-compete the beardtongues or increase the wildfire risk. One commenter stated that Graham’s beardtongue habitat is open and generally devoid of other plant species, suggesting the habitat provides some immunity to crowding from invasive weeds.

Our Response: In our 2013 proposed rule, we documented that weeds alter the frequency, intensity, extent, type, and seasonality of fires (see Summary of Factors Affecting the Species, Invasive Weeds). While weeds are not abundant in beardtongue habitat, they are present, and are abundant in adjacent habitat and where soil disturbance occurs. We considered weeds a future threat in our 2013 proposed rule because the amount of energy development, and associated soil disturbance, expected to occur across these species’ ranges is likely to increase weed prevalence within beardtongue habitat, as well as the likelihood that weeds will increase with climate change. However, in this final rule we determined that the 2014 CA actions will be effective at eliminating or reducing threats to the beardtongues, including the potential threat from weeds.

(48) *Comment:* The PLPCO and SITLA stated that we concluded dust can negatively affect plants, but we did not provide information on: (1) The amount of dust deposited at what distance; (2) the extent to which dust deposition may adversely affect beardtongue growth and reproduction; and (3) whether those adverse effects are likely to reduce the viability of the species. They further stated that stability of two beardtongue research plots adjacent to unpaved roads suggests the effects of fugitive dust may not be significantly adverse to individual plants even on a cumulative basis. Thus, it is speculative to conclude the disturbance from dust is detrimental to these species.

Our Response: Based on existing studies that examined the effects of dust on plants, including those in the Uinta Basin, we found that dust can affect plants up to 1,000 m (3280 ft) away with greater effects closer to the disturbance (Service 2014a, entire). Effects of fugitive dust include changes in species composition, altered soil properties, blocked stomata, reduced foraging capacity of pollinators, dehydration, reduced reproductive output, and a decline in reproductive fitness (see Summary of Factors Affecting the Species, Energy Exploration). However, the establishment of conservation areas that limit disturbance, and the use of spatial disturbance buffers of 91.4 m (300 ft) from plants within conservation areas and on all BLM lands, reduce dust generation near both species thus reducing the threat from dust. The 91.4 m (300-ft) buffer from disturbance will ensure that the greatest impacts from dust, which occur closest to the disturbance, will be reduced.

(49) *Comment:* The PLPCO and other commenters stated that substantial

problems exist with the scientific conclusions and logic concerning the effects of climate change. They contend that, because we acknowledged the correct environmental factors driving reproduction and survival of the beardtongues have not been measured, we have inaccurately characterized the species’ population status and trends. Another commenter stated our argument that climate change impacts will be more severe if energy development destroys and fragments the habitat is speculation and not a basis for finding a cumulative threat to the species. They further stated we provided no factual support that climate change is likely to augment the ability of invasive plants to outcompete native plants.

Our Response: Climate change is occurring, and there is strong scientific support for projections that warming will continue through the 21st century (see Climate Change under *Factor E*). While down-scaled climate models of the Uinta Basin are not available, annual mean precipitation levels are projected to decrease, and air temperatures and periods of drought are expected to increase in western North America. Because the scientific literature, including the citations PLPCO provided in their comments, indicate the importance of precipitation for plant recruitment, we considered future precipitation patterns in our analysis of climate change and the likely reduction of plant recruitment under reduced precipitation and increased incidence of drought. Additionally, soils are expected to dry more rapidly because of increased temperatures and this is likely to result in reduced soil moisture levels in beardtongue habitat (see Summary of Factors Affecting the Species, Climate Change). Climate change impacts likely will be more severe if oil and gas development destroys and fragments the habitat. Development activities in currently unoccupied but suitable habitat for the species could limit the potential range expansion or shifts necessary for both species to adapt to climate change. The 2014 CA creates conservation areas that limit surface disturbance and create spatial buffers so that the cumulative effects of energy development, livestock grazing, small population sizes, invasive weeds, and climate change are reduced.

(50) *Comment:* The PLPCO and SITLA stated that demographic studies (McCaffery 2013a; Reisor and Yates 2011) do not incorporate acceptable sample sizes and analyses as defined by Morris and Doak (2002). Both commenters provided additional citations relevant to population models. They raise several concerns, including:

(1) Limited study locations that do not represent the species' ranges and, therefore, the potential range of demographic variability and environmental stochasticity; (2) the sample contains large detection errors that limit the applicability and statistical rigor of the analyses and are not accounted for in the Population Viability Analysis (McLoughlin and Messier 2004); and (3) the population trend and condition cannot be accurately derived from the study data. Therefore, they contend that a minimum population size for these species cannot accurately be determined.

Our Response: We acknowledge the limitations inherent in the demographic studies on both beardtongue species. We used the best scientific and commercial information available to assess population status and trends for the beardtongues. The demographic studies we cited provide the only long-term population information for both species, and we considered and included those study results in our analysis. We did not establish a minimum population size for either species in our proposed rule or this document; rather, we stated that populations of either species with fewer than 150 individuals are more prone to extinction from stochastic events (see Summary of Factors Affecting the Species, Small Population Size).

(51) *Comment:* The PLPCO and another commenter stated that our assertion that future development will contribute to genetic isolation and reduced adaptive capacity of small populations is not supported. They contend that it is reasonable to assume that both species, as edaphic (soil-related) endemics, are naturally rare and have always occurred in small, isolated populations, and thus genetic effects from isolation may be minimal.

Our Response: We agree that both beardtongues are edaphic endemics that were historically rare. We used genetic studies from other plant species, comprising the best information available at the time, to infer the effects of habitat fragmentation on gene flow within and between beardtongue populations. We determined it is incorrect to assume no gene flow is occurring between populations without genetic studies.

(52) *Comment:* The PLPCO and SITLA stated that, according to the Service, the conservation needs of the species were based upon "expert workshops" rather than actual, available data; and so they suggest that the Service should acknowledge that the best available information may not be sufficient to support the proposed determination.

Our Response: We used information from scientists with expertise in botany and specific knowledge of one or both species, in addition to published literature and data, where available, to evaluate the best available scientific information for both beardtongues in order to complete a status assessment and determine the resource needs for species viability.

(53) *Comment:* The PLPCO stated that we misapplied an existing conservation agreement for the species and did not consider recent efforts to develop a new agreement. The County, State, BLM, and affected industries have been working together to build a comprehensive conservation plan for the two species.

Our Response: We agree that Graham's and White River beardtongue conservation should be pursued by State, local, private, and Federal agencies, and actions to achieve this objective are detailed in the 2014 CA (see Ongoing and Future Conservation Efforts). The 2014 CA provides significant conservation actions to benefit Graham's and White River beardtongue. Conservation measures in the 2007 Conservation Agreement were considered in the proposal, but did not contain sufficient conservation actions to address threats to the species.

(54) *Comment:* The SITLA provided citations of scientific literature that they believe were relevant to our analysis in the 2013 proposed rule, but were not included in the proposed rule.

Our Response: We appreciate the additional citations to support the analysis in the 2013 proposed rule. We have reviewed the information in these studies, but were not able to apply them to this document as they were general in nature and did not specifically address the Graham's and White River beardtongue species or the threats they may face.

(55) *Comment:* Rio Blanco County stated that listing is unnecessary, the proposed rule failed to demonstrate these beardtongue species are being impacted, and our analysis was speculative with respect to impacts identified to occur in the future. The County believed we were attempting to exclude energy development from the area rather than cooperatively seeking effective mitigation measures for developers to demonstrate they can avoid or mitigate such impacts. The County strongly recommended that we consult with the BLM on the conservation of the beardtongues.

Our Response: In our 2013 proposed rule, we stated that the beardtongues were stable species and that substantial threats were currently not occurring. However, we further stated that threats

were likely to occur in the future, at a high intensity and across both species' entire ranges. We have worked cooperatively with various stakeholders, including the BLM, to finalize the 2014 CA to address these identified threats (see Ongoing and Future Conservation Efforts). We determined that the 2014 CA measures will be effective at eliminating or reducing threats to the beardtongues.

(56) *Comment:* Rio Blanco and Carbon counties stated that grazing permittees will be negatively impacted by the proposed rule. They contend that the potential impact and trampling damage from large deer and elk populations were only briefly mentioned, but many beardtongue populations overlap with summer and winter range for mule deer and elk. Additionally, they contend that this area has a huge population of wild horses and it was a flaw not to include this information in the proposed rule.

Our Response: In the 2013 proposed rule, we stated that livestock were likely not the primary grazers of Graham's and White River beardtongue. We updated the section in this document to clarify that wild horses use the habitat areas. We mention some herbivory was attributed to deer (see Summary of Factors Affecting the Species, Grazing and Trampling). We do not have data showing the presence or impacts from elk in beardtongue habitat.

(57) *Comment:* One commenter stated that we failed to discuss obvious management measures to address fragmentation and gene flow. They cited a court case (*CBD v. Norton*, 411F. Supp. 2d 1271, 1290 (D.N.M. 2005)) where the district court rejected arguments that a cutthroat trout species was threatened with extinction from habitat fragmentation and inbreeding because the threat could be "alleviated by management activities" including transplantation.

Our Response: Transplanting and propagation as management activities to address fragmentation and gene flow of either beardtongue species have not been proven to be effective in conserving either species. However, we worked cooperatively with various stakeholders to finalize the 2014 CA, which is considered in this document. This agreement identifies significant conservation actions for both beardtongues on State, private, and Federal lands across their ranges, including the mediation of habitat fragmentation and reduced population connectivity (see Table 1 and Ongoing and Future Conservation Efforts).

(58) *Comment:* Several commenters stated that we provided insufficient evidence that grazing is a threat to the

beardtongues in the proposed rule. One commenter stated that we provided no scientific or field evidence that disease or predation (Factor C) is a threat. Commenters contend that the grazing of grasses is believed to have enhanced the habitat for Graham's beardtongue.

Our Response: We considered predation from many sources in our proposed rule, including grazing by livestock. We concluded in our proposed rule that livestock grazing only impacts the beardtongues when considered cumulatively with increased energy development, invasive weeds, small population sizes, and climate change. We did not consider disease to be a threat to either species, as the best available information does not suggest that disease is impacting Graham's or White River beardtongues. In this listing withdrawal, we have determined that the 2014 CA measures will be effective at reducing threats to the beardtongues.

(59) *Comment:* SITLA and several other commenters stated that we demonstrated population numbers and increases sufficient for these species to remain viable into the future. The commenters stated that the Service and experts agree that both species are stable, thus a listing under the Act is premature, as we should not base a listing on either insufficient data regarding the species' population or populations that are not declining. The commenters stated that as more surveys are conducted, more plants are found, and this demonstrates that the population trends are increasing. The commenters noted that these population increases occurred while the plants faced the same threats that were analyzed in the proposed rules. The commenters stated we must consider these population increases in our listing determination.

Our Response: As survey effort and area has increased, so has the number of plants that have been found. However, an increase in the population due to increased survey area and effort does not indicate that the population is increasing, and we do not have any information to suggest that populations of either species are increasing. Population trends such as increases and decreases are determined by monitoring known occurrences over a period of time. The monitoring data that we evaluated shows that populations for Graham's beardtongue are stable and populations of White River beardtongue are stable or close to stable (McCaffery 2013a, entire; BLM 2011, pp. 6–7).

In the 2013 proposed rule, we stated the beardtongues have stable populations, but faced many threats. Our analysis of the threats, not just the

population size, led to our proposed determination of threatened status for the species. In the 2013 proposed rule, we concluded that, while current threats from energy development are low, these threats are expected to increase in intensity, magnitude, and severity across the range of both species so that they are likely to become endangered in the foreseeable future. The 2014 CA was developed to reduce these and other threats to both beardtongue species.

(60) *Comment:* One commenter stated they are concerned that we proposed to list a plant variety, rather than a species or subspecies. The commenter requested that we perform a more thorough analysis of the uniqueness of White River beardtongue before we conclude this status review.

Our Response: White River beardtongue is one of four varieties of Plateau beardtongue (*Penstemon scariosus*). White River beardtongue is differentiated from the other three varieties of Plateau beardtongue primarily by morphological and geologic substrate differences. The use of the term variety in this instance is equivalent to the definition of a subspecies, which is a taxonomic subunit of a species. Under the Act there are three listable entities: Species, subspecies, and distinct population segments. Because White River beardtongue is a subspecies, it is a listable entity under the Act.

(61) *Comment:* Two commenters stated there is no evidence the Graham's beardtongue population has suffered from gathering or overutilization (Factor B). The commenters noted that seeds and propagation information are available online, and that the species is highly responsive to cultivation in alpine gardens, which indicates the species will respond successfully to revegetation and reclamation measures.

Our Response: We did not consider unauthorized collection to be a threat to either beardtongue species (see Unauthorized Collection). We know of no successful ecological restoration efforts involving either species or of their habitat. Other more common beardtongue species are easily cultivated, but we know of no work that has been conducted on the propagation and restoration of Graham's and White River beardtongues.

(62) *Comment:* One commenter stated that anytime there is a listing under the Act, we are stifling the wise use of natural resources. Another commenter stated the listing under the Act may not be the best way to ensure survival of the species. Survival would be better assured through well-considered mitigation and reclamation design.

Our Response: Under the Act, we must list a species if the best available scientific and commercial information indicates that it meets the definition of a threatened or endangered species.

(63) *Comment:* One commenter stated the penstemon expert meeting notes did not support the Service's conclusion of threatened status. Additionally, they were concerned that the comment period for the proposed rule did not coincide with the flowering period of either plant, so it was not possible to confirm or refute population data.

Our Response: We did not solicit the experts' opinions regarding whether listing under the Act was warranted. The purpose of the meeting was to evaluate the best available scientific information for the beardtongues. We reopened the comment period from May 6–July 7, 2014, to accommodate additional time for the public to make comments. This second comment period overlapped flowering for both beardtongue species, which occurs from May through June.

(64) *Comment:* Two commenters stated their support for the listing of both beardtongues. One commenter stated that the ecosystem is not resilient enough to withstand a decline in biodiversity, and the beardtongues fulfill a very specific niche. The limited range of both beardtongues is a concern, and their low recruitment makes them naturally vulnerable. There is likely no protection on State and private lands from energy development, and impacts on these lands would increase fragmentation of remaining habitat at a landscape scale. Habitat impacts can have a systemic impact on the entire ecosystem beginning with the bee pollinators. Climate change would likely serve as an added stressor. One of the commenters supports the protection of ecologically meaningful core areas to maintain pollinator and plant diversity. They conclude that the argument to protect biological diversity of the oil shale barrens is a strong one and should be considered.

Our Response: Our 2013 proposed critical habitat rule (78 FR 47832) for the beardtongues recognized the importance of preserving plant diversity and pollinators in beardtongue habitat. In the 2014 CA, we identified landscape-level protections necessary to protect the beardtongue species and their pollinators from indirect and cumulative impacts (see Ongoing and Future Conservation Efforts) by establishing conservation areas, surface disturbance limits, avoidance buffers, and measures to address livestock grazing, invasive weeds, small population size, and climate change.

The conservation areas provide connectivity between occurrences and protect large populations that will serve as a core area for the conservation of both species. Other incremental stressors will also be addressed individually in order to reduce the cumulative threats that may be acting on both species.

(65) *Comment:* One commenter stated the existing protections on BLM lands are not adequate to assure the persistence of the beardtongues. A 150-foot buffer is inadequate, and the Vernal RMP does not require avoidance of plants.

Our Response: Conservation areas established in the 2014 CA include adequate buffers (91.4 m [300 ft]) and surface disturbance limits (see Ongoing and Future Conservation Efforts).

(66) *Comment:* Carbon County asked us to consider the economic impacts to people and local economies from the delay or prevention of energy resource development as a result of a listing of either species. One commenter stated that restricting development is in direct conflict with our Nation's energy policy. The commenter was concerned that he/she would need to obtain a Federal air quality permit, which may include restrictions associated with these listings. This outcome would potentially stop oil and gas and oil shale mining activities on their land and impact their family income in excess of \$1 million annually. The commenter indicated that, given the incomplete status of data and understanding, perhaps a threatened species status at this time is premature.

Our Response: An economic screening analysis was completed for our proposed critical habitat designation; however, the Act does not allow us to consider economic impacts in our decision on whether to list a species. Because we are withdrawing the proposed listing and critical habitat rules, the impacts that the commenters are concerned about will not occur.

(67) *Comment:* Several commenters including Duchesne County, Uintah County and SITLA stated that they support the 2014 CA over a decision to list the two species under the Act, and stated that we should take the conservation measures in the 2014 CA into account in our determination of the status of the species. The reasons for their support are sorted into the following categories and explained in greater detail below:

1. **Threats:** The commenters stated that we do not fully know the range and habitat of the two beardtongue species. They concluded that enacting the 2014 CA (instead of listing the species) would

allow time for more surveys so that we will better understand the species population, habitat, and distribution, and allow for conducting transplant and restoration studies on disturbed lands. Also, the commenters concluded that the 2014 CA affords the species landscape-level protection, by including state and private lands in conservation areas.

2. **Conservation on non-federal lands:** The commenters concluded that the 2014 CA affords more protection for both beardtongue species than a listing under the Act, with less economic impact. Under the Act, listed plants are not protected on non-federal lands without a federal nexus; whereas, the commenters state that the 2014 CA provides legally binding protection on approximately 10,000 acres for both species on state and private lands. Additionally, they conclude that the 2014 CA promotes cooperation among landowners and managers.

3. **Implementation and funding:** Uintah County, SITLA, and PLPCO stated that they are committed to implementing the 2014 CA, and the State of Utah Endangered Species Mitigation Fund has enough funding to ensure success of the 2014 CA.

4. **Timeframe:** The commenters state that the 2014 CA can be reassessed at the end of the duration of the agreement and renewed if necessary, or the species can then be listed under Act.

Our Response: The Act does not allow us to consider economic impacts in decisions on whether to list a species under the Act. However, we agree that the 2014 CA provides significant conservation benefits to Graham's and White River beardtongues, including providing landscape-level protections through the inclusion of conservation area protections on non-federal lands; promoting cooperation with federal and non-federal partners; providing non-federal funding and commitments for the conservation of the species; and allowing for more time to better understand the species habitat, abundance, and demography. In addition, the 2014 CA protects 64 percent of the known occurrences of Graham's beardtongue and 76 percent of known occurrences of White River beardtongue throughout the species' ranges by establishing conservation areas where surface disturbance will be limited and plants will be avoided by 91.4 m (300 ft), or unavoidable impacts mitigated. The 2014 CA specifies that, on federal lands, both species will be protected by buffers of 91.4 m (300 ft) from surface disturbing activities both within and outside of conservation areas. Through our Policy for Evaluation

of Conservation Efforts When Making Listing Decisions (PECE) (68 FR 15100, March 28, 2003) process, we determined that these protections were adequate to reduce the threats to the species such that they no longer warrant listing as threatened or endangered.

(68) *Comment:* The SITLA and one other commenter noted that technical experts concluded that current plant populations of both beardtongue species are stable and likely to persist into the future.

Our Response: We agree that the best available information shows that the monitored sites of Graham's and White River beardtongue appear to be stable (McCaffery 2013a, entire; BLM 2011, p. 6–7). We also concluded that both species of beardtongue are likely to persist into the future when considering the protections of the 2014 CA that reduce the threats to the species.

(69) *Comment:* The County Commission of Duchesne County stated that they object to the proposed rules to list Graham's and White River beardtongues and designate critical habitat because the proposed listing rules are not consistent with Duchesne County General Plan policies; the proposed rules are not consistent with State of Utah plans for the subject lands; and the proposed rules will economically adversely affect small businesses and governments.

Our Response: The Act does not allow us to consider economic impacts in decisions on whether to list species. Our proposed listing rules were based on an analysis of the threats to Grahams and White River beardtongues in accordance with the Act. However, since publication of our proposed rules, we have developed a 2014 CA which reduces the threats to the species, and we have concluded that neither species warrants listing under the Act.

(70) *Comment:* Duchesne County asked to be included in the development of recovery plans.

Our Response: We welcome participation by any stakeholder in the development of conservation and recovery efforts for Graham's and White River beardtongues. However, recovery plans pursuant to the Act will not be necessary because we have determined that neither species warrants listing under the Act.

(71) *Comment:* Duchesne County stated that they expect the Service to recognize valid, existing rights including access within critical habitat, such as access to mineral rights.

Our response: We are withdrawing our proposed rules to list Graham's and White River beardtongues and designate critical habitat. Instead we have

determined that the protections of the 2014 CA conserve the species through the designation of conservation areas to the point that these species no longer meet the definition of threatened or endangered. Landowners and managers where these conservation areas will be established are participating in the conservation agreement either directly or indirectly. Within these conservation areas valid, existing landowner rights, including access, will be allowed, but controlled such that new surface disturbance does not occur within 91.4 m (300 ft) of plants, and surface disturbing activities are limited to 5 percent where Graham's beardtongue occurs and 2.5 percent where White River beardtongue occurs.

(72) *Comment:* Many commenters (including 4,890 form letters) supported the listing of Graham's and White River beardtongues because they believe the 2014 CA is not adequate to prevent extinction of both beardtongue species. Their reasons for supporting a listing are sorted into the following categories with further explanation:

1. **Threats:** The commenters stated that the conservation agreement does not prevent or reduce the threats to the species including those from energy development, road construction and maintenance, OHVs, and climate change; the 2014 CA will allow an increase of identified threats to the species in comparison to a listing of the species; the measures addressing grazing are vague and not adequate to conserve the species; the 2014 CA should enact mandatory buffers to protect the species and their habitat; conservation agreements are not as protective as a listing under the Act, especially compared to the protections under Section 9 of the Act; the 2014 CA has no benefits and possible negative impacts to the species on Federal lands; threats such as invasive species are not addressed and measures for these threats are unclear; neither species has protections on state and Federal lands; therefore, more protection is required on Federal lands; the 2014 CA does not provide assurances that impacts to the species will be reduced or mitigated; both beardtongue species are ranked by the UNPS as species of extremely high concern, the highest priority category for conservation; and because both species are considered candidate species, they already meet the criteria for listing under the Act.

2. **Buffers and disturbance thresholds:** The commenters state that the 91.4 m (300 ft) buffer from surface disturbing activities as outlined in the 2014 CA is discretionary and inadequate to protect the plant and its pollinators, whereas

the 700 m (2,297 ft) proposed critical habitat area surrounding known occurrences is more appropriate because it would protect pollinator habitat and genetic movement; buffers of at least 200 m (650 ft) are needed; the 2014 CA allows disturbance of 5 percent for Graham's beardtongue and 2.5 percent for White River beardtongue conservation areas, without a biological basis for allowing surface disturbance caps in the conservation areas; and the 2014 CA does not say how the conservation team will track surface disturbance levels.

3. **Conservation Areas and critical habitat:** The commenters are concerned that the conservation areas in the 2014 CA protect less acreage than the amount of area that was proposed for critical habitat; the larger area proposed for critical habitat was determined in our proposed rule to be "essential to the conservation of the species" and protects the species on a landscape level, including protecting pollinator nesting sites and secondary floral resources; the 2014 CA protects only 76 percent of the population of White River beardtongue and 64 percent of the population of Graham's beardtongue, which the commenters believed was insufficient; the 2014 CA does not provide for the redundancy, resiliency, and representation of either species; and the 2014 CA does not include suitable habitat to address the threat of climate change.

4. **Timeframe:** The commenters expressed concern that the interim conservation areas are not protected over a long enough term and may be developed at any time; additional habitat loss and fragmentation can negatively affect small populations; the 15-year term of the agreement is too short to recover the species whereas a listing under the Act provides protections until the species is recovered; and the agreement terminates if either species is listed.

5. **Implementation and funding:** The commenters stated that the 2014 CA relies on future, voluntary, and unfunded conservation measures that have not been implemented, shown to be effective, and have no certainty of implementation; private landowners have not authorized conservation measures on their lands; the 2014 CA does not include an implementation plan; conservation measures such as transplanting and habitat restoration are unproven; there is no funding identified for all the tasks; voluntary conservation agreements are not proven to adequately protect species from extinction whereas protections under the Act, including listing, have a 99 percent success rate of

preventing extinction; the State of Utah has not committed adequate resources or authority for implementing the 2014 CA; and listing under the Act would be better because it requires recovery planning and Federal funding.

6. **Conservation team:** The commenters expressed concern that the conservation team does not include representatives from all stakeholders, including those from the Utah and Colorado Natural Heritage Programs, Uinta Basin Rare Plant Forum, Red Butte Garden, Utah Division of Oil Gas and Mining, Utah State Lands and Forestry, Utah Division of Wildlife, beardtongue experts, and environmental advocacy groups; the conservation team lacks the expertise to carry out the 2014 CA; the state as a signatory to the agreement does not apply a scientific approach to other natural resource matters; the duties of the conservation team are not adequate to implement all the tasks outlined; the conservation team has not been identified or funded; and the County and State have not previously participated or cooperated in ongoing efforts to conserve rare plant species across the state or in Uintah County.

7. **Other:** The commenters noted that the 2014 CA was developed without public input and all interested stakeholders; the 2014 CA sets a bad precedent; and pursuing a conservation agreement wastes taxpayer's money since this is the third time the species has been proposed for listing under the Act.

Our Response: We used our Policy for Evaluation of Conservation Efforts When Making Listing Decisions to evaluate the certainty that the conservation measures in the 2014 CA will be implemented and effective at reducing threats to Graham's and White River beardtongues. We concluded that the conservation measures in the 2014 CA have a high certainty of being implemented and effective. Our detailed PECE analysis is available for review at <http://www.regulations.gov> and <http://www.fws.gov/mountain-prairie/species/plants/2utahbeardtongues/>. See the Ongoing and Future Conservation Efforts and PECE Analysis sections below for more information. Our response to the comments in each category listed above is as follows:

1. **Threats:** The 2014 CA reduces the threats to the species by providing protections from energy development, invasive weeds, climate change, and small population sizes through the establishment of 44,373 acres of conservation areas where surface disturbance is limited, and where disturbance occurs, it will avoid plants

by 91.4 m (300 ft). In addition, the 2014 CA provides for protections of both species on non-federal lands in key units (conservation areas) that would otherwise not be protected unless a federal nexus occurred. Under Section 9 of the Act, listed plants do not receive protections on non-federal lands unless a federal nexus applies. Therefore, even if listed, many plants occurring on non-federal lands may still be vulnerable to the identified threats. In the 2014 CA, threats from grazing are addressed through a monitoring and adaptive management process where BLM will assess and reduce livestock impacts where they occur. Additional threats from invasive species are reduced through the development and implementation of a weed management plan. OHV use was not considered a threat to the species in our proposed rule; however, establishment of conservation areas and BLM management of their lands for the beardtongue species will minimize the effects of OHVs through consideration of the needs for protection of both species during the development of the BLM travel management plan.

2. Buffers and Disturbance Caps: We have revised the language in the 2014 CA to ensure that adherence to the 91.4 m (300 ft) avoidance buffers is mandatory, rather than discretionary, and exceptions will only be allowed when it is beneficial for the species or its habitat and approved by the conservation team on non-federal lands, or after conference with the USFWS on federal lands (Table 4). The 91.4 m (300 ft) avoidance buffers were selected to protect the species from the effects of surface-disturbing activities because this is the buffer distance that is currently being used under Section 7 consultations under the Act in the Uinta Basin in Utah to avoid direct and indirect effects that are likely to adversely impact listed plant species. This buffer distance is based on a review of literature that shows that, although the effects of dust can extend out to 1,000 m (3,281 ft), and ground disturbance may have additional effects out to 2,000 m (6,562 ft), the greatest impacts occur closer to the disturbance. Thus, 91.4 m (300 ft) was selected to balance the protection of the species with energy development (Service 2014a, entire). Surface disturbance caps of 2.5 percent for White River beardtongue and 5 percent for Graham's beardtongue were selected to minimize habitat fragmentation that can occur from full field (40-acre spacing) development, which results in 13 percent surface disturbance. We will

calculate surface disturbing activities as explained in the 2014 CA (Table 4, conservation action 1) by tracking activities that require a permit, include permanent structures, or construction or expansion of new or existing roads.

3. The acreage included in the conservation areas is less than the acreage that we proposed as critical habitat; the proposed critical habitat for the two beardtongue species overlap, and total 75,846 acres. However, critical habitat protections for plants do not apply on non-federal lands without a federal action; therefore, proposed critical habitat on federal lands alone would typically apply to only 49 percent of the population of Graham's beardtongue and 60 percent of the population for White River beardtongue. The 2014 CA protects a greater number of plants by protecting 64 percent of Graham's beardtongue plants and 76 percent of White River beardtongue plants on both federal and non-federal lands. In addition, the conservation areas are strategically placed to provide habitat connectivity, thereby conserving the resiliency, redundancy, and representation of the species across their ranges (Figure 3; Table 3). The 2014 CA conservation areas include unoccupied habitat on slopes of various aspects that may allow the species to adapt to chosen microhabitats as the climate changes. There are many ways to achieve conservation of these two species. The proposed critical habitat designation identified all populations, with the understanding that critical habitat would not convey or guarantee conservation. The 2014 CA conserves a smaller amount of habitat, but provides greater protection because it actually conserves a greater percentage of the population.

4. Timeframe: We did not rely on the interim conservation areas for our PECE analysis and final determination because the interim conservation areas are subject to development at any time and do not provide certainty of protection for either species. The timeframe of the 2014 CA is 15 years. During this time we hope to better understand the intensity, magnitude, and scale of the threats to both beardtongue species including those from energy and oil shale development. At any time during or near the end of the 15 years, parties to the agreement can choose to continue with and renew the conservation agreement. If during or after this timeframe, either species meets the definition of threatened or endangered, we can act to protect the species through the listing process. If the beardtongue species are listed under the Act, the 2014 CA expires

automatically to avoid a situation where the parties are bound to both the commitments in this agreement and the potentially additive requirements of the Act. This conservation framework provides a consistent regulatory framework for landowners or managers who may be affected, while still protecting the beardtongue species under either scenario.

5. Implementation and funding: Through our PECE analysis process we found that the 2014 CA has a high certainty of being implemented and effective. Our detailed PECE analysis is available for review at <http://www.regulations.gov> and <http://www.fws.gov/mountain-prairie/species/plants/2utahbeardtongues/>.

6. Although the signatories to the conservation agreement include federal, state, and county governments, we welcome participation by any stakeholder or beardtongue expert to provide relevant information and express their viewpoint in the process of administering the 2014 CA. We will reach out to others with knowledge about the two beardtongue species and landowners to ensure they have an opportunity to participate in the conservation of the species as we implement the 2014 CA. Funding for the implementation of the agreement, such as for establishing conservation areas, will be supplied by the various signatories through in-kind services and each land owner or manager will provide funding for conservation measures on their lands, such as surveys prior to surface disturbing activities. The conservation team includes botanists from the BLM and USFWS who are well qualified to provide botanical expertise.

7. The 2014 CA was developed by county, state and federal entities that have the authority to regulate and permit activities on lands within their jurisdiction that overlap with Graham's and White River beardtongue habitat. The protections in the 2014 CA were analyzed through our PECE process and found to have a high certainty of implementation and effectiveness.

(73) *Comment:* A couple of commenters asked us to identify which areas were subject to the 5 percent disturbance limit cap and which areas are subject to the 2.5 percent disturbance limits cap and to make this information public. In addition, one commenter asked for clarification about whether the disturbance caps applied per unit or per landowner. One commenter stated that this information must be available for public comment before the agreement can be finalized.

Our response: We provided a map of the conservation areas (Figure 3; also included in the 2014 CA) showing the areas where the different disturbance caps apply. The disturbance caps apply per landowner per unit (units are shown on Figure 3). The conservation agreement is a voluntary agreement and may be finalized without public comment, although we made the 2014 CA available for comment during our public comment period on the proposed rules and associated draft economic analysis and draft environmental assessment of critical habitat.

(74) *Comment:* One commenter does not agree that the designation of conservation areas or the surface disturbance cap of 5 percent for Graham's beardtongue and 2.5 percent for White River beardtongue included in the 2014 CA is necessary for the protection of either beardtongue species because they do not agree with the science used to support these protections.

Our response: In our proposed rule, we used the best available information to support our conclusions that both Graham's and White River beardtongue need landscape-level conservation and protections, particularly from full-field energy development. The establishment of conservation areas provides the necessary landscape-level conservation, and the surface disturbance caps protect both beardtongue species from full-field development.

(75) *Comment:* One commenter stated that the Service did not follow its own guidance and policy regarding the peer review process for the proposed rules, citing the Service's Information Quality and Peer Review Guidelines (revised June 2012) implementing the Office of Management and Budget's December 16, 2004 Final Information Quality Bulletin for Peer Review. The commenter concluded that the peer review that was conducted by the Service for these proposed rules is not adequate because the peer reviewers did not fully analyze the scientific information presented in the proposed rules nor did they point out important flaws in the Service's analysis. At least one peer reviewer was not objective in their review because they are negative toward the oil and gas industry.

Our Response: As outlined in the proposed rule, we followed our peer review guidance and process for the proposed rules (59 FR 34270; July 1, 1994). We requested peer review from seven peer reviewers, all of whom are knowledgeable about the two beardtongue species. We received completed peer reviews of the proposed rules from four of these peer reviewers.

These peer review comments are included in our administrative record and are available at

www.regulations.gov. We reviewed the documentation provided by the commenter regarding the objectivity of one of the peer reviewers and did not find a conflict. That peer reviewer, as a citizen, submitted a letter to the Colorado Oil and Gas Conservation Commission in support of a larger setback for oil and gas drilling from residential homes. We do not view this action as compromising the objectivity of a peer review of our proposed rules.

(76) *Comment:* One commenter asked us to state the value of the conservation areas to the conservation of the two species: specifically, whether the conservation areas protect known occurrences or only suitable habitat.

Our Response: The conservation areas protect both known occurrences and unoccupied suitable habitat. Of the known occurrences, the conservation areas encompass and protect 64 percent of Graham's beardtongue plants and 76 percent of White River beardtongue plants.

(77) *Comment:* One commenter questions the ability of the conservation team to accomplish all the tasks identified in the 2014 CA, given the lack of knowledge and experience of the conservation team members and lack of funding. The commenter requested that we determine minimum qualifications for conservation team members as well as identified funding.

Our Response: We conclude that the conservation team has the knowledge and ability to carry out the conservation measures in the conservation agreement. The main protection in the 2014 CA is the establishment of conservation areas, which the signatories to the agreement have the authority and ability to implement. The BLM has sufficient expertise in controlling invasive weeds and monitoring and managing livestock impacts to the species because they have been managing grazing allotments since the passage of the Taylor Grazing Act of 1934, and now manage under the Federal Land Management and Policy Act of 1976. We have developed guidelines for surveying and monitoring Federally listed and candidate plant species (Service 2011, entire), and these guidelines will be used to monitor Graham's and White River beardtongues as committed to in the 2014 CA. The BLM has funded and continues to fund demographic monitoring of both species and management of energy development and sensitive plant species protection on their lands. Uintah County and Utah DNR have funded surveys for both

beardtongue species over multiple years.

(78) *Comment:* One commenter questioned whether the populations we report in the 2014 CA for both Graham's and White River beardtongues are genets (i.e., colonies of clones sharing identical genes reproduced vegetatively from the same individual) or ramets (i.e., individual stems or clones from the same genet). The commenter proposes that the population size may be about half of the number we report because ramets may have been counted instead of genets. The commenter acknowledges that others do not agree that the plants are clonal.

Our Response: During transplanting of Graham's beardtongue in 2012, plants were excavated and inspected but clonal reproduction was not observed (Brunson 2012a, entire; Reisor 2014a, entire). Graham's beardtongue may produce multiple rosettes from one branching caudex (stem), but these might represent only 5–10 percent of the population (Brunson 2012a, entire), and these are not thought to contribute greatly to inflated population counts (Reisor 2014a, entire). Based on this information, we conclude that surveys represent accurate counts and that our population estimates are correct based on the best available information.

(79) *Comment:* One commenter stated that several citations in the 2014 CA should be corrected including Kramer *et. al* 2011, which is not relevant to pollination of penstemon species.

Our Response: We have reviewed the 2014 CA, and made the suggested citation changes except for Kramer *et. al* 2011, which is used in the context of genetic relationships between penstemon species.

(80) *Comment:* One commenter recommended that we include pollinator scarcity as a threat.

Our Response: We included pollinator scarcity as an impact under energy development and exploration in the 2014 CA (see Table 4. Threats to Graham's and White River Beardtongues and Associated Conservation Actions). This threat is being reduced by establishing conservation areas and limiting disturbance, which will allow pollinators adequate habitat and secondary floral resources.

(81) *Comment:* One commenter was concerned that we used a lower population number of 11,423 to characterize the population of White River beardtongue compared to the 25,000 as estimated by other sources.

Our Response: Our population number of 11,423 plants of White River beardtongue in the proposed rule was determined from the best scientific and

commercial data available, based on more recent data than the higher population estimate the commenter suggest using. Since the publication of the proposed rule, we received additional survey information that increased our estimate of the population of White River beardtongue to 12,215 plants.

(82) Comment: A couple of commenters stated that we made contradictory conclusions regarding the certainty of oil shale development. The commenters gave examples, such as the Draft Economic Screening Memorandum, which acknowledges the uncertainty of the viability of oil shale development, whereas the proposed rule states that oil shale development is “highly likely.” In addition, the proposed rule concluded that oil shale development will occur sooner, and to a greater extent than concluded by the Draft Economic Screening Memorandum. The commenters concluded that we should revise the estimates of the magnitude of threats from energy development.

Our Response: Based on our analysis as discussed under Summary of Factors Affecting the Species, Energy Exploration and Development, we found that without protections, oil shale development is a threat to the species in the foreseeable future. Our Draft Economic Screening Memorandum assessed only the economic impacts from designating critical habitat, and thus some of the conclusions of the memorandum differ from our assessment of threats to the species, as they are evaluating different questions.

(83) Comment: One commenter stated that the 2014 CA restricts and prohibits the ability of leasees to develop their mineral rights adequately. The commenter stated that the BLM cannot restrict additional surface disturbance on existing leases once the disturbance caps as defined in the 2014 CA are reached.

Our Response: Surface disturbance caps within conservation areas are sufficient to allow reasonable access to existing leases with current technology. BLM has committed to limiting surface disturbance within conservation areas.

(84) Comment: One commenter stated that the 91.4 m (300 ft) buffer around plant occurrences in the draft conservation agreement is too large, and there is no demonstrated need for such a large buffer. Instead, the commenter recommends a 30.5 m (100 ft) buffer with dust suppressant measures.

Our Response: Our review of available literature shows that impacts to plants from dust can extend out to 1,000 m (3,281 ft), and additional impacts from

surface-disturbing activities can extend to 2,000 m (6562 ft) (Service 2014a, entire). The greatest impacts occur closest to the disturbance, and the 91.4 m (300 ft) buffer balances energy development with protection of listed plant species.

(85) Comment: One commenter stated that the 2014 CA should revise the timeframe when surveys should be conducted in relation to surface-disturbing activities, so that surveys must be conducted at least one year prior to surface disturbing activities, and that we should extend the length of time that surveys are valid (currently one year) so that surveys are not outdated prior to the commencement of surface-disturbing activities.

Our Response: The Service has developed guidelines for surveys of listed plant species in Utah (Service 2011, entire). Our guidelines state that surveys for listed plant species are good for one year because seeds may disperse and colonize new areas, or remain in the seed bank until conditions are favorable. We believe this conclusion and our guidelines are still valid.

(86) Comment: One commenter asked us to clarify when plant salvage and mandatory avoidance measures would apply under the implementation of the 2014 CA.

Our Response: Under the terms of the 2014 CA, plant salvage will occur voluntarily when plants are directly impacted by surface-disturbing activities outside of designated conservation areas on non-federal lands. We did not consider plant salvage in our analysis of the effectiveness of the 2014 CA to conserve the species, because these measures are voluntary and cannot be relied upon to protect the species from threats. However, mandatory avoidance measures were evaluated in our PECE process. Mandatory avoidance measures occur within all conservation areas, and within and outside of conservation areas on BLM lands; in these areas surface-disturbing activities will avoid plants by a 91.4 m (300 ft) buffer. Surface-disturbing activities may only occur within 91.4 m (300 ft) of plants if they benefit or reduce impacts to the species or habitat, and, on non-federal lands, may only occur if they are approved by the conservation team, or on federal land, after BLM has conferred with the Service.

(87) Comment: One commenter stated that the BLM cannot incorporate the provisions of the 2014 CA into permits and its RMP without analyzing the impacts through NEPA analysis.

Our Response: The terms of the 2014 CA will be applied to proposed projects

on BLM lands during the NEPA process on those projects, and will thus not require an RMP amendment in order to implement them. In the 2014 CA, the BLM agreed to incorporate the terms of this agreement into its planning process during the next RMP revision, but in the interim the agency will proceed through the NEPA planning and public review process on a project-specific basis.

(88) Comment: One commenter stated that mitigation for impacts to both beardtongue species should be clearly spelled out in the 2014 CA when avoidance by 91.4 m (300 ft) is not possible. In addition, mitigation should be considered for impacts over the 5 percent and 2.5 percent disturbance caps. These mitigation measures should be developed with the involvement of all stakeholders.

Our Response: Surface disturbing activities may only occur within 91.4 m (300 ft) of plants if they benefit or reduce impacts to the species or habitat and, on non-federal lands, if they are approved by the conservation team, or on federal lands, if BLM has conferred with the Service. Mitigation for unavoidable impacts will be determined on a project-specific basis. Successful ecological restoration may be used in conservation areas on private lands to offset effects over the disturbance limits set by the 2014 CA.

(89) Comment: One commenter stated that the May 5, 2014 press release, notice of availability (79 FR 25806), and supporting documents were confusing to the public because they did not clearly present the options to protect the beardtongue species including either signing and enacting the 2014 CA, or listing the species as threatened and designating critical habitat under the Act. In addition we did not provide a PECE analysis.

Our Response: Our document stated that: “We intend to consider this conservation agreement once it has been signed in our final decisions on whether to list Graham’s beardtongue and White River beardtongue under the Act, and invite the public to comment on the agreement and its impact on the conservation of these species, and whether the draft agreement sufficiently ameliorates the threats to Graham’s beardtongue and White River beardtongue. We intend to evaluate this agreement under our Policy for Evaluation of Conservation Efforts When Making Listing Decisions (PECE policy) (68 FR 15100, March 28, 2003; 79 FR 25806, p. 25811).” Our detailed PECE analysis is now available for review at <http://www.regulations.gov> and <http://www.fws.gov/mountain-prairie/species/plants/>

2utahbeardtongues/. See the Ongoing and Future Conservation Efforts and PECE Analysis sections below for more information.

(90) *Comment*: One commenter stated that Graham's and White River beardtongues are different species with different geographical ranges and population demography and should not be lumped together for listing and analysis.

Our Responses: We agree that Graham's and White River beardtongues are different species with different geographical ranges and population demography, and they were considered separately for our listing determination. However, they appear in the same listing document because their ranges overlap and threats to both species are similar.

(91) *Comment*: One commenter encouraged us to list the species without designating critical habitat if we decide to enter into the 2014 CA.

Our Response: We have concluded that the 2014 CA adequately reduces the threats to the species, and we no longer consider either species to be warranted for listing under the Act.

(92) *Comment*: One commenter questioned the participation of State of Utah employees, the Director of SITLA, and Uintah County officials in the 2014 CA because he doubted their commitment to the species' conservation based on their track record with conservation of rare plant species in the past.

Our Response: Through our PECE process we evaluated the conservation measures of the 2014 CA, past conservation actions, and the commitments made by state and local organizations. We determined that the conservation effort, the parties to the agreement that will implement the effort and the staffing, the funding level, the funding source and other resources necessary to implement the effort are identified. Through our PECE analysis we concluded that the conservation measures in the 2014 CA have a high certainty of being implemented and effective.

(93) *Comment*: One commenter stated that increased population estimates for the species may be the result of increased surveys and not indicative of an increasing population trend. The commenter noted that the population estimate of approximately 40,000 Graham's beardtongue plants is more likely to be 20,000 plants because the survey data incorporates surveys over a 35-year period and some of the sites may now be extirpated or reduced in size, or some of the plant may have been misidentified.

Our Response: We used the best available information to determine the known population size of each species (see Background-Graham's beardtongue, *Species Information*, Distribution and Trends). We acknowledge that the best available information may contain counts of plants that no longer occur, but it also may include underestimates of some populations where plant occupancy was documented but counts were not provided, in which case we assumed a count of only 1 plant. All survey information was provided by trained botanists, so it is not likely that plants were misidentified. We agree that as we increase our survey effort the number of plants we find also increases, and that this is not indicative of an increasing population trend.

(94) *Comment*: One commenter stated that increasing temperatures, less rainfall, and increased herbivory, in addition to increased disturbance from roads, dust, and livestock grazing, may push Graham's beardtongue to extinction over the next 25 years. The commenter concluded that the 2014 CA term of 15 years is not sufficient in light of the Enfert mining plan which extends for a period of 30 years.

Our Response: The term of the 2014 CA is 15 years, but can be renewed by any or all parties at that time to continue to conserve both beardtongue species. We will re-evaluate the need for protections under the Act if during or after the period of the 2014 CA either species is warranted for listing as threatened or endangered. See further discussion in the Determination section of this document regarding the foreseeable future of the threats.

(95) *Comment*: One commenter stated that the 2014 CA could be considered sufficient to reduce threats to the species if the termination clause was removed and more permanent protections were committed to, including designating ACECs on BLM lands and conservation easements on private lands.

Our Response: We concluded that the conservation measures in the 2014 CA have a high certainty of being implemented and effective. Our detailed PECE analysis is available for review at <http://www.regulations.gov> and <http://www.fws.gov/mountain-prairie/species/plants/2utahbeardtongues/>. See the Ongoing and Future Conservation Efforts and PECE Analysis sections below for more information.

(96) *Comment*: A few commenters concluded that we overestimated the threats to the beardtongue species, specifically fugitive dust, grazing, OHV use, unauthorized collection, invasive weeds, small population size, and

climate change, and thus the commenters did not support our finding that the beardtongues are in danger of extinction. The commenters furthered concluded that if we find that these factors are not threats to the species individually, then they do not constitute a cumulative threat to the species.

Our Response: We have determined that the 2014 CA adequately addresses threats to the species that were identified in our proposed rule, and the species is no longer considered warranted for listing under the Act.

(97) *Comment*: One commenter concluded that we overstated the threats to the species from future energy development. The commenter stated that energy development is not a threat to the species because populations are stable, predictions of future energy development are not supported, there is no commercial oil shale development in the Uinta Basin, the two beardtongue species are found on steep slopes where energy development is more costly, the density of well pads and size of disturbance from drilling projects are decreasing, and the BLM already provides protection for the species as a candidate species.

Our Response: Our analysis of the threats to the species shows that although populations are currently stable, without the 2014 CA protections they are subject to landscape-level threats from future energy development. See our analysis and discussion of the threats to both beardtongue species from energy development under Summary of Factors Affecting the Species, Energy Exploration and Development.

(98) *Comment*: One commenter supports the conclusions of the proposed rules that energy development including oil shale development and traditional oil and gas drilling poses a threat to the species.

Our Response: We agree that energy development is a threat to the species; however, we have determined that the 2014 CA adequately addresses these threats by establishing conservation areas throughout the range of the species.

(99) *Comment*: One commenter stated that the 2014 CA does not address threats where habitat is leased for both oil and gas development and oil shale development and does not provide information on existing surface disturbance.

Our Response: We have concluded that the 2014 CA addresses the threats of oil shale and traditional oil and gas development by establishing conservation areas, restricting surface disturbance within these conservation areas, and keeping surface disturbing

activities at least 91.4 m (300 ft) from Graham's and White River beardtongues. Calculations of existing surface disturbance are ongoing and will be incorporated into the 2014 CA once they are available.

(100) Comment: One commenter stated that we should provide information regarding the seismic project discussed in the proposed rule.

Our Response: The proposed seismic project is still being evaluated under the NEPA process by the BLM Vernal Field Office. This seismic project encompasses 9 sections in Utah and 5 sections in Colorado. The purpose of the project is to assess the potential for oil and gas development by acquiring information on potential resources present from four parallel seismic lines totaling 7.3 miles. Additional information about the project can be found on the Vernal BLM projects Web page once it is ready for public review at <http://www.blm.gov/ut/st/en/fo/vernal/planning/nepa.html>. As discussed below (see Summary of Factors Affecting the Species, Energy Exploration and Development, *Traditional Oil and Gas Drilling*), we view this project as an indication that traditional oil and gas development will very likely increase in the habitat of both of these species. However, the 2014 CA provides protections to avoid, minimize, and mitigate the impacts of oil and gas development, effectively reducing this threat to the species.

(101) Comment: One commenter stated that climate change alone poses a threat to the species. The Colorado Natural Heritage Program's Colorado Wildlife Action Plan assessed the vulnerability of rare plants to climate change and found that both Graham's and White River beardtongues were extremely vulnerable (June 2011). The Utah Heritage Program model for Graham's beardtongue found that the timing and amount of moisture was important in the distribution of the species. The commenter concluded that we must designate critical habitat to conserve the species instead of relying on the conservation areas delineated in the 2014 CA.

Our Response: We agree that without protections climate change poses a threat to the species when considered cumulatively with other threats. We have concluded that the 2014 CA adequately reduces the threat of energy development by establishing conservation areas that protect 64 percent of the population of Graham's beardtongue and 76 percent of White River beardtongue and that span the range of environmental variation within the species' range. In addition, the 2014

CA addresses climate change with the installation of a weather station and by studying the response of the two species to weather patterns. Once we can better predict the two species' response to climate changes, we can then take measures to address the species' future needs from the threat of climate change. In addition, the 2014 CA provides for the resiliency, redundancy and representation of both species by protecting adequate habitat and an adequate percent of the population in multiple sites that include various slope aspects and important natural community associates and attributes, such as pollinators, pollinator nesting sites, and secondary floral resources.

(102) Comment: One commenter asked us to reconsider the effects of livestock grazing on both species, because there is documentation of the effects of herbivory to reproduction and effects from other herbivores that contribute to lost reproduction, trampling effects on pollinators, declining habitat conditions with several allotments within the range of both species needing improvement, and low and sporadic reproduction making it vulnerable to stochastic events and habitat changes.

Our Response: We agree that without conservation protections, livestock grazing poses a threat to both species in conjunction with other threats including energy development. We have addressed these threats in the 2014 CA, which states that BLM will monitor impacts from grazing and will adjust grazing regimes accordingly to reduce associated impacts.

(103) Comment: A commenter stated that small population size poses a threat to the species because small populations that are fragmented are more vulnerable to habitat changes and disturbances. The commenter cited a demography study (McCaffery 2013a, entire) that shows that neither species is stable, and both species are threatened by small population sizes and habitat fragmentation.

Our Response: We agree that, without protections, small population size is a threat to the two beardtongue species when considered cumulatively with other threats. However, we reviewed the same study cited by the commenter and came to a different conclusion about the stability of these populations. Available studies indicate the monitored sites for Graham's beardtongue are stable (McCaffery 2013a, p. 15; BLM 2011, p. 6–7). For White River beardtongue, one site was found to be stable and a second site was close to stable with a very low chance of extinction over the next 50 years (McCaffery 2013a, p. 15). The

2014 CA protects 64 percent of Graham's beardtongue, and 8 of the occurrences protected in conservation areas have a 7 percent or lesser chance of extinction, and 4 occurrences have less than a 2 percent chance of extinction over the next 50 years (McCaffery 2013a, entire; Service 2014d, entire). The 2014 CA protects 76 percent of White River beardtongue, and 4 of the occurrences protected in conservation areas have a less than 1 percent chance of extinction over the next 50 years (McCaffery 2013a, entire; Service 2014d, entire).

(104) Comment: One commenter stated that Graham's beardtongue has been surveyed sufficiently and both Graham's and White River beardtongues are some of the most surveyed species in Utah. Baseline surveys from 1978 and 1979 show that Graham's beardtongue have declined since that time period.

Our Response: The best available information based on continuous and consistent monitoring of Graham's and White River beardtongue from 2004 to 2012 does not indicate that the populations of either species are declining (BLM 2011, pp. 6–7; McCaffery 2013a, entire).

(105) Comment: One commenter stated that at 12,215 plants, the population of White River beardtongue is low enough to be considered for listing as endangered. The commenter noted that about one-third of the population occurs on BLM lands. The commenter noted that the population of this species is precarious. Another commenter indicated that populations of both beardtongue species in Colorado are small, and thus warranted for protection under the Act.

Our Response: As discussed below under Summary of Factors Affecting the Species, Small Population size, some species exhibit rarity but are not warranted for listing under the Act. A species that has always been rare, yet continues to survive, could be well equipped to continue to exist into the future. Many naturally rare species have persisted for long periods within small geographic areas, and many naturally rare species exhibit traits that allow them to persist despite their small population sizes. Consequently, the fact that a species is rare does not necessarily indicate that it may be in danger of extinction in the foreseeable future. Rarity is a characteristic that may increase a species' vulnerability to factors such as demographic stochasticity, environmental stochasticity, genetic stochasticity, and natural catastrophes. However, whether a given rare species is affected by any of these factors, and the magnitude of

the effect of these factors on the species' ability to persist into the foreseeable future, is species- and context-specific. Consequently, in general the Service does not consider rarity alone to be a threat, unless there is information identifying threats to the species and linking those threats to the rarity of the species.

In this case, the current population size of White River beardtongue in and of itself does not mean that it is endangered or threatened. The best information that we have about the population indicates that White River beardtongue is stable (McCaffery 2013a, entire; BLM 2011, p. 6–7), and we have concluded that the 2014 CA sufficiently protects the species from threats. The large occurrence of White River beardtongue that occurs on BLM lands is protected in a conservation area.

(106) Comment: One commenter stated that we must consider that the BLM conservation measures, such as the 91.4 m (300 ft) buffer to protect the species, are not enforceable, have not been adhered to in at least one Section 7 consultation, and the BLM travel management plan will not be sufficient to protect the species from OHV impacts.

Our Response: The Secretary of the Interior (Secretary) has the authority to manage oil and gas operations on Federal lands. The Secretary has delegated this authority to the Bureau of Land Management (BLM), which has issued onshore oil and gas operating regulations codified at 43 CFR part 3160. The operating regulations at 43 CFR 3164.1 authorize the BLM's Director to issue Onshore Oil and Gas Orders when necessary to implement and supplement the operating regulations. In addition 43 CFR 3162.5–1 that deals with environmental obligations provides that, “the operator shall comply with the pertinent orders of the authorized officer and other standards and procedures as set forth in the applicable laws, regulations, lease terms and conditions, and the approved drilling plan or subsequent operations plan.” BLM also has the authority to determine whether planned activities adhere to their policies and if they will adversely impact sensitive species. Therefore, BLM conservation measures are enforceable. We have determined in our PECE analysis that the conservation measures are likely to be implemented and effective. See the Ongoing and Future Conservation Efforts and PECE Analysis sections below for more information. Off-highway Vehicle use was not considered a threat to the species, but the 2014 CA includes provisions to ensure that it does not

become a threat in the future (see Summary of Factors Affecting the Species, Off-highway Vehicle Use).

(107) Comment: One commenter stated that our proposed rules did not adequately address representation, redundancy, or resiliency as was defined and considered in the listing of the Preble's Meadow Jumping Mouse (73 FR 39790).

Our Response: We adequately address resiliency, redundancy and representation of the species in this document and in the 2014 CA conservation measures. We address resiliency of the species by conserving an adequate amount of the species habitat and populations through the establishment of conservation areas and limiting surface disturbance within these areas. We address the redundancy of the species by ensuring there are enough occurrences of the species throughout its range by establishing conservation areas in each conservation unit throughout the range of the species. We provide for the representation of the species by conserving its community associates through establishing conservation areas that encompass these associates. Our analyses of representation, resiliency and redundancy are specific to the species we are evaluating. Therefore, the details of our analysis for Graham's and White River beardtongues differ from the Preble's Meadow Jumping Mouse analysis.

(108) Comment: One commenter stated that our proposed rules did not provide sufficient resiliency for either species as they should protect suitable unoccupied habitat on other slopes to allow for species' movement as a result of climate change.

Our Response: We do not have predictive information detailing how Graham's and White River will respond to climate change in terms of what areas they may need as refugia. However, both the proposed critical habitat and the 2014 CA conservation areas include unoccupied habitat on slopes of various aspects that should allow the species to adapt to chosen microhabitats as the climate changes. As we are able to better understand both species responses to climate change, we can work with the conservation team to modify conservation areas to accommodate the species needs.

(109) Comment: One commenter concluded that any analysis under our PECE policy should find that the 2014 CA is not adequate because it is not certain to be implemented and not certain to be effective.

Our response: We concluded that the conservation measures in the 2014 CA

have a high certainty of being implemented and effective. Our detailed PECE analysis is available for review at <http://www.regulations.gov> and <http://www.fws.gov/mountain-prairie/species/plants/2utahbeardtongues/>. See the Ongoing and Future Conservation Efforts and PECE Analysis sections below for more information.

(110) Comment: One commenter stated that conservation areas that were established in 2014 CA but not evaluated in our proposed critical habitat rule should not be considered until they can be determined to be suitable for the species. Another commenter requested clarification on what information was used to establish the conservation area boundaries.

Our Response: The conservation area boundaries were drawn based on plant occurrences, densities, and population sizes over the range for each species. We used a kernel density analysis in ArcGIS (Brunson 2013, entire) of known occurrences to identify areas of high density occurrences which have a lower probability of extinction over the next 50 years (McCaffery 2013a; entire). Conservation areas include the beardtongue species, insect and community associates, corridors between occurrences, and additional buffers and habitat for pollinators.

Summary of Changes From the Proposed Rule

Based upon our review of the public comments, comments from other Federal and State agencies, peer review comments, issues raised at the public hearing, and new relevant information that has become available since the publication of the proposal, we have reevaluated our proposed listing rule and made changes as appropriate. Other than minor clarifications and incorporation of additional information on the species' biology and populations, this determination differs from the proposal in the following ways:

(1) Based on our analyses of the potential threats to the two species and the protections provided by the 2014 CA, we have determined that neither Graham's nor White River beardtongue meets the definition of a threatened or endangered species. This document withdraws our proposed rule as published on August 6, 2013 (78 FR 47590). Subsequently, this document also withdraws our proposed rule to designate critical habitat for these species (78 FR 47832, August 6, 2013).

(2) We have added a discussion of Ongoing and Future Conservation Efforts, below. The conservation measures in the 2014 CA are included in this section.

Ongoing and Future Conservation Efforts

Below we review conservation efforts for Graham's and White River beardtongues, including those in the 2014 CA. We describe the significant conservation efforts that are already occurring and those that are expected to occur in the future. We have also completed an analysis of the newly initiated and future conservation efforts pursuant to our Policy for Evaluation of Conservation Efforts When Making Listing Decisions (PECE) (68 FR 15100, March 28, 2003).

After our withdrawal of the listing for Graham's beardtongue in 2006 (71 FR 3158, January 19, 2006; 71 FR 76024, December 19, 2006) several stakeholders initiated conservation measures for the species as outlined in a 2007 Conservation Agreement and Strategy (2007 CAS) for Graham's beardtongue; these conservation measures included plant surveys, 91.4-m (300-ft) avoidance buffers on BLM lands, and a demography study that has been ongoing since 2004. In our 2013 proposed rule, we determined that these conservation measures were no longer sufficient to address the threats to the Graham's beardtongue and did not specifically address threats to White River beardtongue. Since 2007, Utah DNR, BLM, and Uintah County have implemented many of the conservation measures as described in the 2007 Conservation Agreement.

Despite the positive accomplishments of the 2007 Conservation Agreement, our 2013 proposed rule identified several threats that would negatively act on Graham's and White River beardtongues and their habitat in the future. Threats identified in the 2013 proposed rule included: (1) Energy

exploration and development; and (2) cumulative impacts of increased energy development, livestock grazing, invasive weeds, small population sizes, and climate change. We also determined that existing regulatory mechanisms were not adequately addressing the future threats from energy development (78 FR 47590, August 6, 2013).

Based on information provided in our proposed rule, land managers, Uintah and Rio Blanco Counties, and State agencies established a 2014 CA and conservation actions to address the identified threats. The 2014 CA includes the most recent Graham's and White River beardtongue survey information and establishes conservation areas that will be managed with limited surface disturbance and avoidance buffers for individual plants (see Table 3; Figure 3; 2014 CA, entire), as further described below. The 2014 CA also includes measures to address the cumulative impacts from energy development, livestock grazing, invasive weeds, small population sizes, and climate change, in addition to the inadequacy of regulatory mechanisms identified in our proposed rule (78 FR 47590, August 6, 2013). The term of the conservation agreement is for 15 years, but can be renewed depending on the success of the conservation agreement and if signatories are willing. After the 15-year period, we hope to better understand the intensity and timeframe of oil shale development, the species distribution within its range, as well as responses to livestock grazing so that any future conservation agreement can address those factors appropriately.

The conservation areas designated in the 2014 CA are designed to ensure redundancy, resiliency, and representation of the species across their

ranges. A species can be conserved (and is thus viable) if it has adequate representation, resiliency, and redundancy (Shaffer and Stein 2000). Representation, or preserving some of everything, means conserving not just a species but its associated plant communities, pollinators, and pollinator habitats. Resiliency and redundancy ensure there is enough of a species so that it can survive into the future. Resiliency means ensuring that the habitat is adequate for a species and its representative components, and populations are of sufficient size to withstand stochastic events. Redundancy ensures an adequate number of sites. This methodology has been widely accepted as an appropriate conservation methodology (Tear *et al.* 2005, p. 841).

The boundaries of the conservation areas in the 2014 CA were selected to encompass large populations to ensure species' viability and smaller populations to provide connectivity and represent the range of the species. The designated conservation areas include approximately 17,957 ha (44,373 ac) (Figure 3; Table 3). Graham's beardtongue is divided into five units, and White River beardtongue is divided into three units, similar to the units that were identified in the proposed rule to designate critical habitat (78 FR 47832). We are using units because the boundaries of element occurrences or populations continue to change rapidly as previously unsurveyed suitable habitat is surveyed and more plants are found causing population boundaries to expand and/or merge. Total number of plants for each species within each unit of the conservation areas is shown in Table 3.

TABLE 3—NUMBERS OF GRAHAM'S AND WHITE RIVER BEARDTONGUE PLANTS BY UNIT IN CONSERVATION AREAS

Unit	Total number of Graham's beardtongue plants	Number of plants (and %) in conservation area	Total number of White River beardtongue plants	Number of plants (and %) in conservation area
1. Sand Wash	2,488	1,842 (74%)	N/A	N/A
2. Seep Ridge	8,760	6,693 (76%)	N/A	N/A
3. Evacuation Creek	21,665	12,238 (56%)	2,070	1,620 (78%)
4. White River	7,383	4,966 (67%)	9,705	7,171 (74%)
5. Raven Ridge	37	37 (100%)	440	439 (99%)
Total	40,333	25,776 (64%)	12,215	9,230 (76%)

Within designated conservation areas for Graham's beardtongue, surface disturbance will be limited to an additional 5 percent new surface disturbance, and within designated conservation areas for White River beardtongue surface, disturbance will be

limited to an additional 2.5 percent of new surface disturbance. Where surface disturbance occurs in designated conservation areas, the disturbance will avoid plants by at least 91.4 m (300 ft). On BLM-managed lands, Graham's and White River beardtongue plants will

also receive the protection of 91.4-m (300-ft) avoidance buffers at all locations where the plants are found (i.e., including areas outside of designated conservation areas). Where disturbance must occur within 91.4 m (300 ft) of plants, mitigation measures

must be included in project actions
(Table 4; Conservation Action 6).

Mitigation will be designed to offset
impacts so that the entire effect of

mitigation is as beneficial or better than
a 91.4 m (300-ft) avoidance.

**TABLE 4—CONSERVATION MEASURES IN THE 2014 CONSERVATION AGREEMENT FOR GRAHAM'S AND WHITE RIVER
BEARDTONGUE (2014, CA ENTIRE)**

Threat and associated impacts	Conservation action
Energy Exploration and Development Habitat loss/fragmentation	1. Conservation areas totaling 17,957 ha (44,373.4 ac) will be established by the Agreement. These conservation areas include 2,382 ha (5,886.9 ac) on private and state lands. Within these conservation areas, development and surface disturbance will be minimized and consolidated to reduce habitat fragmentation, and new surface disturbance minimized in conservation areas by the following actions: • Limiting new surface disturbance to 5 percent per unit on federal lands and by landowner on non-federal lands for Graham's beardtongue, and 2.5 percent per unit on federal lands and by landowner on non-federal lands for White River beardtongue. Units are shown in Figure 3. • Avoiding plants by 91.4 m (300 ft). Surface disturbing activities may only occur within 91.4 m (300 ft) of plants only if it benefits or reduces impacts to the species or habitat. On non-federal lands surface disturbance within 300 ft of either species will need to be approved by the conservation team. On federal lands if surface disturbance is within 300 ft of either species BLM will first conference with USFWS. • Calculating new surface disturbance from those activities that include a permanent structure, activities that require a permit, or new roads or improvements to existing roads in order to track new surface disturbance and ensure disturbance does not exceed thresholds in this agreement 3. Successful ecological restoration may be used in conservation areas on private lands to offset disturbance limits.
Direct mortality from surface disturbance	4. On federal lands, ground-disturbing activities including oil and gas exploration and development will conform with BLM special-status plants species policies, and these species will be treated as a BLM sensitive species. Within designated conservation areas, the BLM will do the following: • Limit new surface disturbance to 5 percent per unit for Graham's beardtongue and 2.5 percent per unit for White River beardtongue • Survey for plants within 91.4 m (300 ft) of proposed disturbance • Avoid disturbance within 91.4 m (300 ft) of plants. Surface disturbing activities may occur within 91.4 (300 ft) of plants only if it benefits or reduces impacts to the species or habitat. When this occurs BLM will first conference with USFWS. • Minimize and consolidate development to reduce habitat fragmentation Outside conservation areas on federal lands, ground-disturbing activities will be sited to avoid Graham's and White River beardtongue plants by 91.4 m (300 ft). 5. On non-federal lands in a conservation area or interim conservation area, new ground-disturbing activities including oil and gas exploration and development proponents will follow these procedures: • Pre-site surveys will be conducted to determine presence and locations of plants (see Survey and Monitoring requirements in table notes) • Exploration and development will be limited to 5 percent new surface disturbance for Graham's beardtongue and 2.5 percent new surface disturbance for White River beardtongue (high-density core population areas on non-federal lands are shown in Maps 20–26 of Appendix A) • Avoid plants by 91.4 m (300 ft). Surface disturbing activities may occur within 91.4 m (300 ft) of plants only if it benefits or reduces impacts to the species or habitat and is approved by the conservation team. 6. On federal and non-federal lands where new surface disturbance will occur in a conservation area within 91.4 m (300 ft) of plants, the project proponent will mitigate for impacts. Within 1 year of signing the Agreement, the conservation team will develop a standardized procedure to address how mitigation is to occur depending on level of impacts. Examples of mitigation could include payments into a mitigation fund for minor impacts, protection of other occupied areas at a ratio specified by the conservation team, or site-specific mitigation appropriate to each project as determined by the conservation team. 7. On non-federal land outside conservation areas and interim conservation areas with approved exploration or plan of operations permits, conservation actions are encouraged but voluntary. Good faith, voluntary actions could include avoidance, minimizing impacts to individual plants, seed collection, plant salvage and transplant, and experimental reclamation and restoration treatments. See conservation actions 1–3 described in "Habitat loss/fragmentation" above.
Indirect disturbance from surface disturbance, including increased dust; introduction and spread of invasive, non-native plant species; and habitat fragmentation.	
Community and habitat loss and disturbance from surface disturbance, including soil and vegetation removal.	See conservation actions 1–3.
Restricted pollinator movement, mortality and disturbance from roads and associated traffic, and energy emissions.	See conservation actions 1–3.
Increased sedimentation and erosion	See conservation actions 1–3.
Pollinator scarcity	See conservation actions 1–6.

TABLE 4—CONSERVATION MEASURES IN THE 2014 CONSERVATION AGREEMENT FOR GRAHAM'S AND WHITE RIVER BEARDTONGUE (2014, CA ENTIRE)—Continued

Threat and associated impacts	Conservation action
Inadequacy of Existing Regulatory Mechanisms Lack of range-wide protection	See conservation actions 1–7. 8. The BLM will ensure that ongoing and future BLM actions support or do not preclude the species' conservation. All projects in designated conservation areas and their potential to impact the species will be reported in the conservation team's annual report. 9. The BLM will retain Graham's and White River beardtongues on the BLM special-status species list as a sensitive species with new ground-disturbing activities avoiding plants by 91.4 m (300 ft) (inside and outside conservation areas), and ensure that the effects of proposed projects are analyzed for the species. 10. The BLM will consider land exchanges with state and private landowners to expand or otherwise enhance the value of conservation areas on federal lands and facilitate the long-term persistence and recovery of the species, while protecting the long-term economic sustainability of the area. 11. The BLM will incorporate the provisions of this Agreement or the latest amendments to this Agreement into its Resource Management Plan planning process, permitting requirements, agency planning documents and budgets. Within 3 months of the signature date of the Agreement, the BLM will incorporate the provisions of this plan into permits and budgets. During the next planning cycle, the BLM will incorporate the provisions of this Agreement into their RMP planning process. The conservation team will provide an annual report on the implementation of this Agreement. The report will also include monitoring results and adaptive management recommendations. 12. If federal land within a conservation area is transferred to the State of Utah, the state agrees to maintain the designated conservation areas and protections for the two species in the transferred parcels, or place lands of comparable or greater value to the conservation of the species in conservation areas within the same species unit as approved by the conservation team. 13. Uintah County will enact an ordinance with associated enforcement protocols and penalties that adopts the conservation measures in this Agreement, including limiting new surface disturbance in conservation areas to 5 percent for Graham's and 2.5 percent for White River beardtongue and avoiding impacts to plants by 91.4 m (300 ft) in designated conservation areas on non-federal and non-state lands, within 3 months after the signing of this Agreement. 14. SITLA will enact a regulation, order, or lease stipulation, as applicable, within 3 months of signing the Agreement that will limit new surface disturbance to 5 percent for Graham's and 2.5 percent for White River beardtongue, and avoid impacts to plants by 91.4 m (300 ft) in designated conservation areas or interim conservation areas on SITLA lands. 15. The conservation team will develop and implement a scientifically valid monitoring plan (approved by consensus) to determine trends in plant populations across the range of the species. The plan should include continued monitoring at the current sites established by Red Butte Gardens, and establish additional monitoring sites to capture range-wide variation in habitat, climate, and population processes. 16. The conservation team will coordinate annual seed collections in all areas where the species are present (with landowner approval), in accordance with USFWS and Center for Plant Conservation (CPC) guidelines, for placement in storage at Red Butte Garden and the National Center for Genetic Resources Preservation. A seed collection plan will be developed and implemented with approval from the USFWS.
Loss of plants/habitat under federal land-ownership/management.	See conservation actions 8–11 and 15–16.
Loss of plants/habitat under non-federal ownership/management.	In conservation areas on non-federal lands, conservation actions 5–7 and 12–16 will minimize and mitigate any loss of individual plants and habitat. 17. On SITLA interim areas (Class A: 682 ha [1,686.6 ac], Class B: 724 ha [1,789.8 ac]) and private interim areas (140 ha [345.5 ac]) prior to approval of any exploration or plan of operations, these areas will also have a limit of 5 percent new disturbance for Graham's and 2.5 percent for White River beardtongue from baseline as set forth in conservation action 14. In the event there are surface-mine plan filings that would necessitate the destruction or removal of habitat, SITLA or the landowner, upon election to convert all or part of an interim conservation area to a non-conservation area, will require pre-disturbance surveys, and to the extent feasible in its reasonable judgment, after consultation with the conservation team, salvage a minimum of 50 plants or 25 percent of the total population size, whichever is greater, and collect seed from 50 plants or 25 percent of the total population size for long-term conservation at Red Butte Garden of identifiable plants from the disturbance area. To the extent feasible, pre-disturbance surveys should be initiated a minimum of 1 year prior to surface-disturbing activities. To the extent feasible, plants should be salvaged in late fall to maximize survival and likelihood of transplant success. Transplant and monitoring of salvaged plants will be overseen by the conservation team.

TABLE 4—CONSERVATION MEASURES IN THE 2014 CONSERVATION AGREEMENT FOR GRAHAM'S AND WHITE RIVER BEARDTONGUE (2014, CA ENTIRE)—Continued

Threat and associated impacts	Conservation action
	18. On private lands, conservation actions on occupied habitats outside of designated conservation areas will be entirely voluntary. Plant and seed salvage and other good faith efforts to protect plants and restore habitat will be considered, but will not be mandatory. The conservation team is expected to work with private entities to promote and provide support for conservation actions on private lands, and will consider creation of a conservation credit system for plant salvage, habitat banking, support of conservation initiatives, and other voluntary activities that promote the persistence and recovery of the species. The conservation team should also promote voluntary restoration and habitat banking or exchanges by private landowners, where landowners would restore occupied habitat or dispersal corridors in anticipation of the need for future revisions of conservation areas on their property or by other private landowners. Allocation or allowances for landowner credits for conservation banks or exchanges would be subject to the authority of the conservation team. The conservation team would also determine how restored populations and habitats would be utilized.
Habitat loss and fragmentation	See conservation actions 1–3.
Livestock Grazing on BLM-Managed Lands	
Herbivory of all or part of aboveground portion of vegetative portion of plant.	19. On federal lands where the species co-occur with livestock grazing during the growing season (April through September), the BLM will develop and implement a mitigation and monitoring plan for each allotment within 1 year of signing this Agreement. If monitoring identifies that livestock grazing is negatively affecting the species, the BLM will immediately adjust livestock management in the allotment to ameliorate those impacts. Short-term adjustments may include construction of temporary drift fences to keep livestock away from occupied habitat, and long-term adjustments may include permanent fencing or modifying the grazing schedule. In any adjustment made to allotments, the authorized officer will include consultation, cooperation and coordination with affected permittees, as stipulated in 43 CFR 4130.3–3. The conservation team will be consulted as necessary. The conservation team will be apprised of changes and modifications to management of allotments through annual reporting to the conservation team.
Herbivory of all or part of the inflorescence.	See conservation action 19.
Trampling of plant and habitat	See conservation action 19.
Change in community composition	See conservation action 19.
Invasive species invasion, spread, and competition.	See conservation actions 19 and 20–24.
Alteration of soil characteristics	See conservation action 19.
Road Construction and Maintenance	
Direct mortality from surface disturbance	See conservation actions 1–3.
Invasive species invasion, spread, and competition.	See conservation actions 20–24.
Increased dust emissions	See conservation actions 1–3.
Restricted pollinator movement from roads.	See conservation actions 1–3.
Habitat loss/fragmentation	See conservation actions 1–3.
Invasive Weeds	
Invasion and establishment of non-native plants.	20. Within 1 year of signing the Agreement, the conservation team will develop, fund, and implement a weed management plan (approved by consensus) in conservation areas that includes repeated annual targeted surveys to detect invasions and treatment of invasive species as soon as detected. This plan can be incorporated as part of a range-wide monitoring plan.
	21. The weed management plan will identify treatment options for each known invasive species in the habitat of the species, with the goal of selecting the most appropriate option that controls weeds and minimizes adverse effects to Graham's or White River beardtongues and their native plant community.
	22. The conservation team will develop and implement a monitoring protocol in the weed management plan to determine the effectiveness of their actions.
	23. The conservation team will review and update the weed management plan annually based on surveys, monitoring, and other information sources, and create an annual schedule of work targeting priority areas.
	24. The weed management plan will develop and adopt best management practices for preventing the spread of invasive and/or exotic plants in the designated conservation areas on federal and non-federal lands.
Competition	See conservation actions 20–24.
Community alteration	See conservation actions 20–24.
Small Population Size	
Stochastic events	See conservation actions 1–7 and 15–16.
	25. Historical locations of <i>Penstemon scarious</i> var. <i>albifluvis</i> near the western end the species' range should be revisited for collection of new voucher specimens and samples for genetic testing. The conservation team will plan and implement a distribution/genetics study to determine overlap and/or division between <i>Penstemon scarious</i> var. <i>garettii</i> and <i>Penstemon scarious</i> var. <i>albifluvis</i> geographic ranges as part of this Agreement.
Inbreeding depression	See conservation actions 1–7, 15–16, and 25.
Lower sexual reproduction	See conservation actions 1–7, 15–16, and 25.

TABLE 4—CONSERVATION MEASURES IN THE 2014 CONSERVATION AGREEMENT FOR GRAHAM'S AND WHITE RIVER BEARDTONGUE (2014, CA ENTIRE)—Continued

Threat and associated impacts	Conservation action
Loss of genetic diversity	See conservation actions 1–7, 15–16, and 25.
Climate Change.	
Mortality caused by drought	26. As part of demographic monitoring of the species, a component will be included to study the relationship between precipitation patterns and species' growth, reproduction and recruitment, and mortality. This may be accomplished by establishing weather-monitoring equipment at existing long-term demographic sites currently monitored by Red Butte Garden.
Stress, lack of reproduction and recruitment, and mortality caused by shifting rainfall patterns.	See conservation action 26.
Habitat degradation	See conservation actions 1–3.
Wildfire	
Mortality	27. Any wildfire planning, suppression activities, and post-wildfire actions on federal and non-federal lands in occupied habitat will include mitigation consistent with the Agreement and include pre-season input from the conservation team.
Community composition alteration	See conservation actions 20–24 and 27.
Post-fire response ground disturbance ...	See conservation action 27.
Increased invasion and competition from invasive species.	See conservation actions 20–24 and 27.
Off-Road Vehicles	
Direct mortality	28. On BLM lands, traffic will be limited to designated routes, and routes will be considered for closure, limited use, or re-routing as appropriate to gain compliance and protect designated conservation areas. This will not include any routes claimed by Uintah County as public roads.
Increased dust load	29. On non-federal lands where off-highway vehicle (OHV) use occurs, wherever possible, landowners and managers will attempt to re-route OHV use away from designated conservation areas and keep traffic on existing roads and trails.
Fragmentation of habitat	See conservation actions 1–3.

¹ Survey/Monitoring/Best Management Practices:

Prior to any surface disturbance in federal and non-federal conservation areas, surveys will be conducted within the area of disturbance and out to 91.4 m (300 ft) from the edge of the disturbance to determine species presence, population, and distribution. Surveys will follow standard survey protocol as detailed in the USFWS *Utah Field Office Guidelines for Conducting and Reporting Botanical Inventories and Monitoring of Federally Listed, Proposed and Candidate Plants* (2011).

On all federal and non-federal lands, the landowner/manager will collect seeds and/or salvage a portion of plants from areas to be disturbed to ensure genetic representation of the species. Seeds can be used for restoration but at least a portion of these seeds should be given to Red Butte and Denver botanic Gardens for long-term storage.

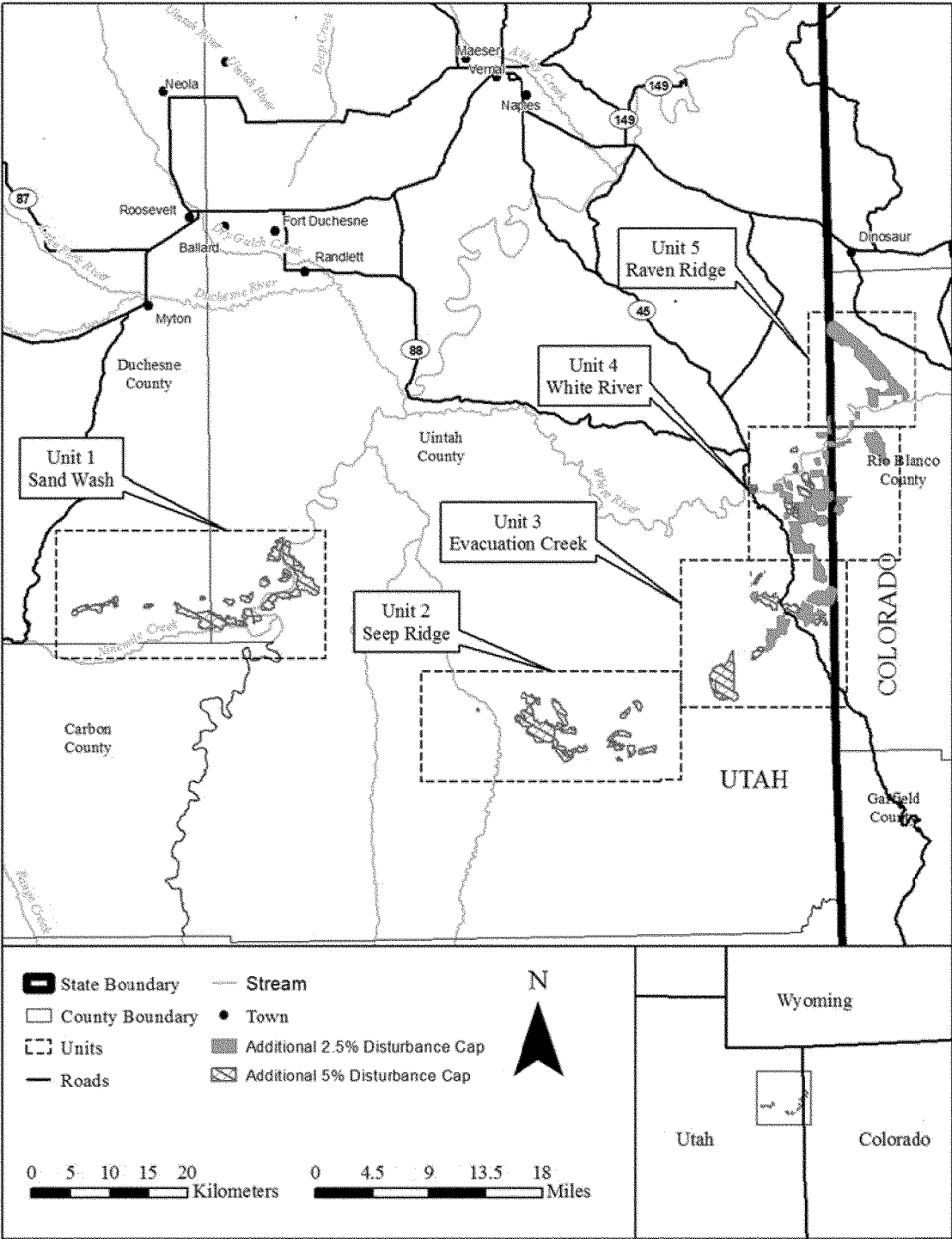


Figure 3: Designated conservation areas for Graham’s and White River beardtongues delineated by units, with notation of the areas where the different disturbance caps apply.

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The 2014 Conservation Agreement will result in the protection of 64 percent of Graham’s beardtongue and 76 percent of White River beardtongues within designated conservation areas. These totals include protections across

the range of both species on Federal, State, and private lands (Table 5). The remaining Graham’s beardtongue plants on BLM lands outside of the designated conservation areas (representing an additional 4% of the total population) will be protected by a 91-m (300-ft)

spatial buffer (all known White River beardtongue plants on BLM lands are within conservation areas). This conservation measure is consistent with BLM protections for the species since 2007. For our analysis of whether the 2014 Conservation Agreement

sufficiently protects both species, we did not consider plants in conservation areas designated as interim, as these

areas provide only short-term protections. Although these areas may in the future be converted to

permanently designated conservation areas, they do not provide assurances for the long-term benefit of the species.

TABLE 5—CONSERVATION AREAS BY LANDOWNER FOR GRAHAM'S AND WHITE RIVER BEARDTONGUES

Species	Land owner-ship	Size of conservation area in hectares (acres)*	Number of plants	Percent of population
Graham's	BLM	15,579 (38,497)	18,702	46.4
	State	1,254 (3,099)	2,319	5.75
	Private	1,128 (2,787)	4,755	11.8
	Total	17,957 (44,373)	25,776	63.9
White River	BLM	8,678 (21,444)	7,482	61.2
	State	343 (847)	177	1.5
	Private	1,170 (2,890)	1,571	12.9
	Total	10,213 (25,238)	9,230	75.6
Both species combined	Total	17,957 (44,373)		

PECE Analysis

The purpose of PECE is to ensure consistent and adequate evaluation of recently formalized conservation efforts when making listing decisions. The policy provides guidance on how to evaluate conservation efforts that have not yet been implemented or have not yet demonstrated effectiveness. The evaluation focuses on the certainty that the conservation efforts will be implemented and the certainty that the conservation efforts will be effective. The policy presents nine criteria for evaluating the certainty of implementation and six criteria for evaluating the certainty of effectiveness for conservation efforts. These criteria are not considered comprehensive evaluation criteria. The certainty of implementation and the effectiveness of a formalized conservation effort may also depend on species-specific, habitat-specific, location-specific, and effort-specific factors. We consider all appropriate factors in evaluating formalized conservation efforts. The specific circumstances will also determine the amount of information necessary to satisfy these criteria.

To consider that a formalized conservation effort contributes to forming a basis for not listing a species, or listing a species as threatened rather than endangered, we must find that the conservation effort is sufficiently certain to be (1) implemented, and (2) effective, so as to have contributed to the elimination or adequate reduction of one or more threats to the species identified through the section 4(a)(1) analysis. The elimination or adequate reduction of section 4(a)(1) threats may lead to a determination that the species does not meet the definition of

threatened or endangered, or is threatened rather than endangered.

An agreement or plan may contain numerous conservation efforts, not all of which are sufficiently certain to be implemented and effective. Those conservation efforts that are not sufficiently certain to be implemented and effective cannot contribute to a determination that listing is unnecessary, or a determination to list as threatened rather than endangered. Regardless of the adoption of a conservation agreement or plan, however, if the best available scientific and commercial data indicate that the species meets the definition of “endangered species” or “threatened species” on the day of the listing decision, then we must proceed with appropriate rulemaking activity under section 4 of the Act. Further, it is important to note that a conservation plan is not required to have absolute certainty of implementation and effectiveness in order to contribute to a listing determination. Rather, we need to be certain that the conservation efforts will be implemented and effective such that the threats to the species are reduced or eliminated.

Using the criteria in PECE (68 FR 15100, March 28, 2003), we evaluated the certainty of implementation (for those measures not already implemented) and effectiveness of conservation measures in the 2014 CA pertaining to Graham's and White River beardtongues. We determined that the measures will be effective at eliminating or reducing threats to the species because they protect occupied and suitable habitat from the effects of energy development, livestock grazing, invasive weeds, small population size

and climate change, by instituting on-the-ground protections to better manage and regulate disturbance in occupied habitat and habitats likely used by pollinators. We have a high degree of certainty that the measures will be implemented because the conservation team partners have a track record of implementing conservation measures for these species since 2007. Over approximately the past 6 years of implementation, BLM, the Utah Department of Natural Resources, and Uintah County have effectively implemented conservation measures from the 2007 Conservation Agreement for Graham's beardtongue including surveying and monitoring the populations of both species, and implementing avoidance buffers from ground-disturbing activities on BLM lands.

New conservation measures are prescribed by the 2014 CA and are already being implemented (see Table 3), including additional surveys and genetic studies. The 2014 CA has sufficient annual monitoring and reporting requirements to ensure that all of the conservation measures are implemented as planned, and are effective at removing threats to Graham's and White River beardtongues and their habitat. The collaboration between the Service, Uintah County, Rio Blanco County, the Utah Division of Wildlife Resources (UDWR), SITLA, PLPCO, and BLM requires regular conservation team meetings and involvement of all parties in order to fully implement the conservation agreement. Based on the implementation of previous actions of members of the conservation team, we have a high level of certainty that the

conservation measures in the 2014 CA will be implemented and effective, and thus they can be considered as part of the basis for our final listing determination for Graham's and White River beardtongues.

Our detailed PECE analysis is available for review at <http://www.regulations.gov> and <http://www.fws.gov/mountain-prairie/species/plants/zutahbeardtongues/>.

Summary of Factors Affecting the Species

Section 4 of the Act (16 U.S.C. 1533), and its implementing regulations at 50 CFR part 424, set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, we may list a species based on any of the following five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; and (E) other natural or manmade factors affecting its continued existence. Listing actions may be warranted based on any of the above threat factors, singly or in combination. Stressors that fall under each of these factors are discussed below individually. We then summarize where each of these stressors or potential threats falls within the five factors.

In 2008 and 2012, we participated in expert workshops—including experts from The Nature Conservancy, Red Butte Garden, the Utah Natural Heritage Program (UNHP), the Colorado Natural Heritage Program (CNHP), BLM, and the Natural Resources Conservation Service to evaluate the best available scientific information for Graham's and White River beardtongues (The Nature Conservancy 2008, entire; Service 2012c, entire). We used the information from these workshops to complete a species status assessment for both Graham's and White River beardtongues. We determined that both species need the following resources for viability:

- Suitable soils and geology.
- Sufficient number of pollinators.
- Intact associated and adjacent plant community (both within and outside of suitable or occupied habitat).
- Minimum reproductive effort or reproductive success.
- Suitable microclimate conditions for germination and establishment.
- Sufficient rain and temperatures suitable for breaking seed dormancy and

successful reproduction (natural climate).

- Minimum habitat patch or population size.
- Genetic diversity or heterozygosity.
- Habitat connectivity and integrity.
- Viable, long-lived seedbank.
- Minimum number of individuals.
- Minimum number of viable populations.

The general list is the same for both Graham's and White River beardtongues because they grow in similar habitats in the same geographic area, even overlapping in places. However, specifics for each resource can differ between the two species.

To determine the current and future status of Graham's and White River beardtongues, through our species status assessment we evaluated if these resource needs are currently met and how these resources are likely to change in the future. If the resources are not currently met or are predicted to be unmet in the future, we determined the cause of the resource insufficiency. The underlying stressor causing the resource insufficiency is then considered as a potential threat to Graham's and White River beardtongues. We discuss these stressors in the following section.

Energy Exploration and Development

In our 2013 proposed rule, we concluded that energy development was a threat to Graham's and White River beardtongues because the species' ranges overlap almost entirely with oil shale and tar sands development areas, and traditional oil and gas drilling.

Potential impacts from energy exploration and development include the removal of soil and vegetation when unpaved roads, well pads, evaporation ponds, disposal pits, and pipelines are constructed (BLM 2008a, pp. 448–449). Increased disturbance from these developments, coupled with climate change (see Climate Change, below), would facilitate the invasion and spread of nonnative species such as cheatgrass (*Bromus tectorum*), halogeton (*Halogeton glomeratus*), purple mustard, and Russian thistle (*Salsola tragus*) (Brooks and Pyke 2001, entire; Grace *et al.* 2001, entire; Brooks 2003, p. 432; Friggens *et al.* 2012, entire), which can outcompete native plants and increase the risk of catastrophic wildfires (see Wildfire and Invasive Weeds, below).

Energy development also results in increased road traffic and subsequent increases in dust emissions; for every vehicle travelling 1 mile (1.6 km) of unpaved roadway once a day, every day for a year, approximately 2.5 tons of dust are deposited along a 305-m (1,000-ft) wide corridor centered on the road

(US Forest Service 1983, entire).

Excessive dust can clog plant pores, increase leaf temperature, alter photosynthesis, and affect gas and water exchange (Sharifi *et al.* 1997, p. 842; Ferguson *et al.* 1999, p. 2, Lewis 2013, entire), negatively affecting plant growth and reproduction. Dust can affect plants up to 1,000 m (3,280 ft) away from the source (Service 2014a, entire). Effects of fugitive dust include species composition changes, altered soil properties, blocked stomata, reduced foraging capacity of pollinators, dehydration, reduced reproductive output, and a decline in reproductive fitness (Service 2014a, entire). A 300-ft buffer is the minimum distance needed in order to protect sensitive plant species (Service 2014a, p. 9).

Roads may act as a barrier to pollinator movement, for example by influencing bees to forage on only one side of the road (Bhattacharya *et al.* 2003, pp. 42–43) or within isolated habitat patches (Goverde *et al.* 2002, entire). Although bees and other pollinators are quite capable of crossing roads or other human-disturbed areas, the high site fidelity of bumblebees makes them more apt to remain on one side of a disturbed area (Bhattacharya *et al.* 2003, p. 42). The implications of this type of pollinator behavior for rare plants is that the probability for outcrossing is reduced (Cane 2001, entire), thereby reducing genetic variability and reproductive success.

Habitat loss or fragmentation from energy development can result in higher extinction probabilities for plants because remaining plant populations are confined to smaller patches of habitat that are isolated from neighboring populations (Jules 1998, p. 1; Soons 2003, p. 115). Habitat fragmentation and low population numbers pose a threat to rare plant species' genetic potential to adapt to changing environmental conditions (Mathies *et al.* 2004, pp. 484–486). Smaller and more isolated populations produce fewer seeds and pollen, and thus attract fewer and a lower diversity of pollinators (Paschke *et al.* 2003, p. 1,258; Lienert 2004, p. 62); for a more complete discussion, see Small Population Size, below.

2014 CA protections—The 2014 CA establishes 17,957 ha (44,373 ac) of conservation areas on private, State, and public lands across the range of both beardtongue species—encompassing 64 percent of the known Graham's beardtongue individuals and 76 percent of the known White River beardtongue individuals. New surface disturbance acreage will be limited in designated conservation areas to 5 percent for Graham's beardtongue and 2.5 percent

for White River beardtongue by landowner within each unit. The allowed new surface disturbance of 5 percent of the current baseline for Graham's beardtongue is higher than the 2.5 percent of the current baseline allowed for White River beardtongues, due to the larger range of the Graham's beardtongue. This is less disturbance than the Utah standards for traditional oil and gas well pad spacing, which is roughly equivalent to 13 percent surface disturbance per section when considering one well per 40 acres and an average surface disturbance of 5.2 acres for each and associated infrastructure (Utah Administrative Code R649-3-2. Location and Siting of Vertical Wells and Statewide Spacing for Horizontal Wells). In addition, any limited surface disturbance within designated conservation areas will avoid plants by 91.4 m (300 ft). This avoidance distance will provide habitat and connectivity for pollinators and minimizes the effects of disturbance, which are greatest closest to the source. In addition, 300 ft is the standard avoidance buffer distance recommended to Federal agencies in the Service's Section 7 consultations on nontribal lands for listed plants within the Uinta Basin based on a review of relevant literature (Service 2014a).

The BLM will institute additional protections on lands it manages outside of designated Conservation Areas by requiring surveys and avoidance of plants by 91.4 m (300 ft) from surface-disturbing activities. This measure protects an additional 1,631 plants of Graham's beardtongue or 4.0 percent of the total population so that a total of 68 percent is protected by spatial buffers both within and outside of conservation areas. All but one White River beardtongue plant on BLM lands are incorporated into the conservation areas. In addition, the 91.4-m (300-ft) spatial buffer protects Graham's and White River beardtongue plants that may be found on BLM lands in future surveys.

Any unavoidable impacts to individual plants will be offset by mitigation, such as protecting additional plants by adding new conservation areas or with contributions to a conservation fund that will be used to support conservation efforts for the plant species. Overall, the establishment and management of conservation areas reduces the threats of surface disturbance, dust emissions, pollinator barriers, and habitat loss and fragmentation from energy development to Graham's and White River beardtongues by protecting an adequate amount of the species' (and associated

pollinator) habitat and populations (Table 3 and Table 5), limiting surface disturbance, and maintaining buffer distances from known and future locations of plants on BLM lands. Limited surface disturbance within conservation areas will reduce potential fugitive dust and pollinator barriers impacts that otherwise may occur with full field development of oil and gas. Although we expect oil and gas development to continue with negative effects to a small percent of both populations, a large percent of the population of both species will be protected by implementing the measures in the conservation agreement. Therefore, we no longer consider energy development to be a threat to the species.

Oil Shale and Tar Sands

The Energy Policy Act of 2005 (42 U.S.C. 13201 *et seq.*) establishes that oil shale, tar sands, and other strategic unconventional fuels should be developed to reduce the nation's dependence on imported oil. The Energy Policy Act (42 U.S.C. 15927(m)(1)(B)) identifies the Green River Region, including the entire range of Graham's and White River beardtongues, as a priority for oil shale and tar sands development. Provisions of the Energy Policy Act of 2005 provide economic incentives for oil shale development. For example, the restrictions in the Mineral Leasing Act of 1920 (30 U.S.C. 181 *et seq.*) limited oil shale lease sizes to 2,072 hectares (ha) (5,120 acres (ac)), and restricted leasing opportunities to just one lease tract per individual or corporation. Lease size restrictions effectively limited development because of a lack of available acreage to accommodate necessary infrastructure and facilities. The Energy Policy Act of 2005 now allows an individual or corporation to acquire multiple lease tracts up to 20,234 ha (50,000 ac) in any one State, loosening the restrictions of the Mineral Leasing Act of 1920 (Bartis *et al.* 2005, p. 48).

As we discussed in our January 19, 2006 (71 FR 3158), and August 6, 2013 (78 FR 47590), proposed rules, Graham's beardtongue is closely associated with the richest oil shale-bearing strata in the Mahogany ledge, which makes the species highly vulnerable to extirpation from potential oil shale or tar sands mining (Shultz and Mutz 1979, p. 42; Neese and Smith 1982, p. 64; Service 2005, p. 5). The economic and technological feasibility of oil shale and tar sands development was uncertain when the original proposed listing rule was withdrawn in 2006 (71 FR 76024,

December 19, 2006). However, in 2013, the BLM issued the OSTEIS for commercial leasing for oil shale and tar sands development in Colorado, Utah, and Wyoming. The 2013 OSTEIS Record of Decision (ROD) opens 145,848 ha (360,400 ac) in Utah and 10,522 ha (26,000 ac) in Colorado for oil shale leasing (BLM 2013a, p. 27), and 52,609 ha (130,000 ac) in Utah for tar sands leasing (BLM 2013a, p. 48).

Leasing for oil shale development on BLM lands has not yet occurred except for eight Research Development and Demonstration (RD&D) leases (1 in Utah and 7 in Colorado) (BLM 2013a, p. 15), but the area open for oil shale leasing and steps needed to gain access to leases on these lands is authorized through the OSTEIS ROD (BLM 2013a, entire). Tar sands leasing on BLM lands is not restricted by the RD&D process, and leases may be obtained through an expression of interest and the BLM mineral leasing process.

In Utah, 33 and 52 percent, respectively, of Graham's and White River beardtongues' total populations of known individuals overlap the BLM-designated oil shale and tar sands leasing areas (Service 2014b, entire; Table 7 and Table 8). Designated oil shale leasing areas in Colorado do not overlap known populations for either beardtongue species and are at least 32 km (20 mi) away from the closest known populations (Service 2013, p. 7).

A majority of all known Graham's beardtongue and White River beardtongue plants are directly associated with the Mahogany ledge where it outcrops or is less than 152 m (500 ft) below the surface (Service 2013, p. 5). Surface strip mining is likely to be the preferred extraction method in areas with shallow overburdens (BLM 2012, p. A-22; Institute for Clean and Secure Energy 2013, p. 6), resulting in the complete loss of all surface vegetation.

About 48 percent and 39 percent, respectively, of Graham's and White River beardtongues occur on State and private lands where they were afforded little protection at the time of our proposed rule. We estimate that most known Graham's and White River beardtongues on State and private lands occur where the Mahogany layer outcrops or is less than 152 m (500 ft) below the surface, making these areas more likely to be surface mined. As a result, plants in these areas are the most vulnerable to direct loss as oil shale and tar sands development expands across the region. In addition, land ownership throughout the Uinta Basin is a checkerboard of private, State, and Federal ownership. Losses of Graham's and White River beardtongue

populations on private and State lands would result in indirect impacts from habitat fragmentation and the loss of population connectivity.

The Utah Division of Oil, Gas and Mining (UDOGM) has approved one large-scale oil shale mine for Red Leaf Resources, Inc., and six other exploration mines for oil shale, which overlap the ranges of Graham's beardtongue and White River beardtongue on private and State lands. In addition, two more permits for oil shale development, one for a small-scale mine and one for a large-scale mine, have been submitted to UDOGM for oil shale development on private or State lands. Red Leaf Resources, Inc., also announced that its field pilot test conducted in 2008 to 2009 performed as predicted, and they will begin their commercial operation when their regulatory permits are finalized (Red Leaf 2013a, entire; Red Leaf 2013b, entire). Red Leaf has filed a Notice of Intent to commence mining operations (Red Leaf 2014; entire), which was approved by UDOGM on Feb 20, 2014, and a subsequent amendment was approved on May 5, 2014 (UDOGM 2014, entire). A third oil shale development company has identified 2,833–3,642 ha (7,000–9,000 ac) for subsurface mining and is currently working through the National

Environmental Policy Act (NEPA) process with BLM (BLM 2013e, p. 1). In our 2013 proposed rule (78 FR 47590), we knew of three oil shale projects and explorations that were planned or ongoing on private, State, and BLM lands in Uintah County, Utah. As of March 2014 we know of five planned and ongoing projects for oil shale on private and State lands, including commencement of commercial scale development (Table 6).

Private and State lands (including SITLA lands) do not have the multistep regulatory requirements that Federal lands have, and they are presently available for oil shale development (Institute for Clean and Secure Energy 2013, p. 5). In addition, the oil shale resources on SITLA lands have, "the potential to support a sizeable commercial shale industry, and its resources are readily developable" (Institute for Clean and Secure Energy 2013 p. 5). The SITLA has sold oil shale leases that overlap both species and includes 23 percent and 9 percent of the total known populations of Graham's beardtongue and White River beardtongue, respectively.

A market study of development of oil shale found that ex-situ extraction methods would break even at market values for oil at \$77.32 to \$91.65 per barrel including hurdle costs,

depending on the technology, with air-fired technology at the lower end (Institute for Clean and Secure Energy 2013, pp. 140–142). Enefit Energy estimates operating costs for oil shale energy development to be considerably lower at \$35 per barrel (Enefit 2014, entire). Crude oil prices for Utah have been above \$78 per barrel in 27 of the past 36 months (January 2011–December 2013) with annual averages above \$82 per barrel from 2011 to 2013 (US EIA 2014a, entire). Forecasts show that prices are to remain above the threshold of \$78 per barrel through the end of the analysis period of 2015 (EIA 2014b, p. 28). In addition, the reference price for oil is expected to be above \$92 per barrel from 2015 to 2040 (US EIA 2014c, p. 6). Despite the current lack of commercial-scale oil shale operations, the technology is feasible, the resource is available—35,701 ha (88,220 ac) of SITLA lands have been leased, 145,848 ha (360,400 ac) of Federal lands in Utah will be made available for leasing after conducting RD&D projects, Red Leaf filed a Notice of Intent in 2014 to commence a large scale oil shale mining operation, and crude oil prices are projected to remain at favorable levels. All these factors lead us to conclude that oil shale development is highly likely to happen in the future.

TABLE 6—CURRENT AND PROPOSED OIL SHALE AND TAR SANDS ON STATE AND PRIVATE LANDS AFFECTING GRAHAM'S AND WHITE RIVER BEARDTONGUES

Project	Project status	Maximum disturbance ¹ Graham's beardtongue (percent of population)	Maximum disturbance White River beardtongue (percent of population)	Protection under 2014 CA ²
Enefit American Oil	NEPA process ongoing	15.2	24.4	2,900 acres in conservation area.
Red Leaf Resources	Utah Division of Oil, Gas and Mining (UDOGM) large mine permit active.	3.8	0.17	0
Ambre Energy	UDOGM small mine permit active	0.75	8.1	< 10 acres in interim conservation area.
TOMCO Energy	UDOGM large mine permit in process.	15.4	0	1,053 acres in interim conservation area—likely to be developed during the 15-year 2014 conservation agreement.
PetroDome North America	UDOGM small mine permit in process.	3.3	0.6	0
TOTAL		38.25	32.87	

1. Maximum disturbance assumes that all beardtongues on the entire property owned or leased are affected by oil shale development operations.

2. Conservation areas will abide by the conditions of the 2014 Conservation Agreement (CA) for the 15-year term of the CA. Interim conservation areas will follow the measures of the 2014 CA until such time as the lessee is ready to develop, which may be shorter than a 15-year time-frame. Interim conservation measures were not considered in our analysis as they provide only temporary protection to the species.

Tar sands extraction is also technically feasible (Institute for Clean and Secure Energy 2013, p. 12). Tar sands lease areas on BLM lands overlap 20 and 0.1 percent of the total known populations of Graham's and White

River beardtongues, respectively. The impacts of tar sands mining will be similar to those from oil shale mining. We are aware of only one approved tar sands project in Utah (Service 2014, p. 3), and the project does not overlap with

any known populations of Graham's or White River beardtongues. There are three active exploration permits on record with UDOGM and one proposed exploration project (Service 2014c, p. 3). None of these projects overlap with

known locations of either beardtongue species.

In summary, the project initiation and the recent BLM leasing decisions indicate the renewed interest in oil shale and tar sands mining and the increased likelihood of development across the ranges of these two species. Over 60 percent of Graham's beardtongue and White River beardtongue plants are directly associated with shallow outcroppings of the Mahogany ledge, which are likely to be surface mined, resulting in the complete loss of vegetation. We estimate that as much as 81 and 91 percent of the total known populations of Graham's and White River beardtongues, respectively, would be vulnerable to direct loss and indirect negative impacts such as habitat fragmentation from oil shale and tar sands development without additional protections. However, the 2014 CA provides protections to avoid, minimize, and mitigate the impacts of oil shale and tar sands development, including the establishment of conservation areas and use of surface-disturbance avoidance buffers, effectively reducing threats to the species (see discussion of 2014 CA Protections under Energy Exploration and Development). The establishment of conservation areas will reduce the threats to the species from oil shale and tar sands development by protecting 64 percent and 76 percent of Graham's and White River respectively from large-scale surface disturbance and habitat fragmentation. Therefore, we no longer consider oil shale and tar sands development to be a threat to the species.

Traditional Oil and Gas Drilling

Historically, impacts to both beardtongue species from traditional oil and gas development were largely avoided because development within the species' habitat was minimal. However, the previously described Energy Policy Act of 2005 enables leasing of oil and gas and tar sands separately, even when the two are found in the same area. Previously, the law required a combined tar sands/oil and gas lease, effectively delaying leasing and extraction of oil and gas in tar sand areas because of concerns about conflicts between tar sands and traditional oil and gas development. Overall, the Energy Policy Act of 2005 effectively opened the entire range of both species to leasing for oil and gas development and made that leasing more efficient and effective.

At the time of publication of our 2013 proposed rule, the impacts of traditional oil and gas development on Graham's

and White River beardtongues were expected to be high (BLM 2008b, p. 457). Although a high level of development within these species' habitats was not yet realized, we expected it to increase in the future. Most of the ranges of Graham's and White River beardtongues are underlain with deposits of traditional hydrocarbon resources, primarily natural gas (Service 2013, p. 8). In the past two decades, oil and gas production in Uintah County, Utah, has increased substantially. For example, oil production in Uintah County increased about 60 percent from 2002 to 2012, and gas production increased about 25 percent over this same time period (UDOGM 2012, entire). Drilling activities in Uintah County continue to increase: The number of new wells drilled in Uintah County was 316 in 2009, 631 in 2012 (UDOGM 2012, entire), and 521 in 2013 (UDOGM 2014, entire).

To update and quantify how much drilling has occurred within Graham's and White River beardtongues' habitat, we used the following methods to identify an analysis area for impacts to the species based upon the currently known plant locations and adjacent essential pollinator habitat. For Graham's beardtongue, we created an analysis area using known locations plus a distance of 700 m (2,297 ft) for pollinators. For White River beardtongue, we created an analysis area using known locations plus a distance of 500 m (1,640 ft) for pollinators. These distances (700 m and 500 m) were based on pollinator travel distance for important pollinators for each species (see *Species Information*, "Biology" for each plant, above) and also matched our proposed critical habitat designation (78 FR 47832; Aug. 6, 2013). We then calculated the number of wells currently drilled within these areas.

Within the Graham's beardtongue analysis area, well drilling has occurred at a comparatively slow pace thus far: As of March 2014, 88 well pads were developed or approved within the analysis area for Graham's beardtongue, and the majority (75) of these are in Utah (Service 2014b, entire), which also corresponds to the majority of the range of the species. We do not know the area of actual surface disturbance associated with each well, so we estimated 2 ha (5 ac) of surface disturbance per well pad (BLM 2008b, p. 4–3), including disturbance from associated roads and pipelines. Accordingly, we estimate that 103 ha (255 ac) of Graham's beardtongue habitat are disturbed from energy development, which is less than 1 percent of the total area included within

the analysis area across the Graham's beardtongue's range.

Development within the White River beardtongue analysis area is similar; as of March 2014, 21 well pads were developed or approved in the White River beardtongue analysis area, 13 of which are in Utah (Service 2014b, entire). Less than 1 percent (26 ha (65 ac)) of the total area included within the White River beardtongue analysis area is likely disturbed by existing oil and gas activities.

Approximately 27 percent of the analysis areas for Graham's beardtongue and 13 percent for White River beardtongue, respectively, on State and Federal land are leased for traditional oil and gas development (Service 2014b, entire). At the time of this analysis, one planned seismic exploration project overlaps with habitat for both beardtongue species. The initiation of this project indicates that traditional oil and gas development will very likely increase in the habitat of both of these species. Our estimate of impacts is likely an underestimate because we do not have information about how much private land is planned for development.

Although some oil and gas drilling has impacted individuals of Graham's and White River beardtongues, development is not at a high enough level to negatively impact the species. Populations monitored for 9 years have been stable (Dodge and Yates 2011, entire), and neither beardtongue appears to suffer from pollinator limitation (Lewinsohn and Tepedino 2007, entire; Dodge and Yates 2009, p. 12). However, substantial numbers of Graham's and White River beardtongue individuals (and their habitat) occur in areas that are leased for oil and gas development (Tables 5 and 6), and thus it is reasonable to conclude that the impacts of oil and gas activity will increase in the future as additional areas are developed. However, the 2014 CA provides protections to avoid, minimize, and mitigate the impacts of oil and gas development, including the establishment of conservation areas and use of surface-disturbance avoidance buffers, effectively reducing threats to the species (see discussion under 2014 CA protections under Energy Exploration and Development section above). Therefore, we no longer consider traditional oil and gas development to be a threat to the species.

Summary of All Energy Development

Since our proposed rule (78 FR 47590) we have learned of additional planned oil shale projects that overlap

known Graham's or White River beardtongue plant locations. If these projects are fully implemented, their direct impacts would reduce the redundancy and representation of both species. Although commercial production of oil shale and tar sands is in its infancy, the commencement of several large projects and State permitting of one large oil shale mining operation indicates progress toward imminent future development of oil shale and tar sands resources within the

range of these species. Without protective measures (i.e., 2014 CA), approximately 86 and 100 percent of the total known populations of Graham's and White River beardtongues (including those in the center of their ranges) are vulnerable to direct loss and the effects of increased disturbance. Approximately 62 and 40 percent of Graham's beardtongue and White River beardtongue, respectively, are on BLM lands within areas that are either leased for oil and gas development or open to

leasing for oil shale and tar sands; approximately 86 and 100 percent of all known Graham's and White River beardtongue plants fall within areas that are open for oil shale and tar sands leasing (see Table 7 and Table 8). Of all known Graham's and White River beardtongue plants, 27 and 12.5 percent, respectively, fall within areas that are leased by the BLM and the State of Utah for traditional oil and gas development.

TABLE 7—POTENTIAL DISTURBANCE TO GRAHAM'S BEARDTONGUE ACROSS ALL LANDOWNER TYPES PRIOR TO AND AFTER ENACTMENT OF THE 2014 CONSERVATION AGREEMENT (CA)

Graham's beardtongue	Percent of population vulnerable to disturbance without 2014 CA Protections		Percent of population vulnerable to disturbance with 2014 CA Protections	
	Number of plants	Percent of total	Number of plants	Percent of total
Existing BLM oil and gas leases	4,619	11.5	770	2
BLM oil shale and tar sands lease areas	13,449	33	910	2
Total number of plants that overlap with all energy types on BLM lands or leases	16,085	40	1,436	4
Existing State of Utah oil, gas, and oil shale leases	11,212	29	9,458	23
Private lands (we assume all of these lands are open to energy development of any kind)	8,525	21	3,761	9
Total number of plants that overlap with all energy types across all landowners	35,126	87	14,345	36

TABLE 8—POTENTIAL DISTURBANCE TO WHITE RIVER BEARDTONGUE ACROSS ALL LANDOWNER TYPES PRIOR TO AND AFTER ENACTMENT OF THE 2014 CONSERVATION AGREEMENT (CA). NUMBERS MAY NOT SUM DUE TO ROUNDING

White River beardtongue	Percent of population vulnerable to disturbance without 2014 CA protections		Percent of population vulnerable to disturbance with 2014 CA protections	
	Number of plants	Percent of total	Number of plants	Percent of total
Existing BLM oil and gas leases	1,238	10	1	<0.001
BLM oil shale and tar sands lease areas	5,899	48	0	0
Total number of plants that overlap with all energy types on BLM lands or leases	7,038	58	1	0
Existing State of Utah oil, gas and oil shale leases	1,276	10	1,100	9
Private lands (we assume all of these lands are open to energy development of any kind)	3,458	28	1,884	15
Total number of plants that overlap with all energy types across all landowners	11,772	96	2,985	24

However, as described above (Energy Exploration and Development, 2014 CA Protections) and in our PECE analysis, the 2014 CA provides additional protections, including the establishment of conservation areas and use of surface disturbance avoidance buffers, effectively reducing threats from energy development to the species. Therefore, we no longer consider energy development to be a threat to either species.

Grazing and Trampling

In our 2013 proposed rule we found grazing to be a contributing factor to cumulative threats to the species, but

not a threat by itself (see Cumulative Effects from All Factors, below). Invertebrates, wildlife, and livestock graze directly on individuals of Graham's and White River beardtongues (Sibul and Yates 2006, p. 9; Dodge and Yates 2010, p. 9; 2011, pp. 9, 12; UNHP 2012, entire). Grazers feed on all parts of the plant, including the seeds, damaging or destroying individual plants and effectively reducing their reproductive success.

It is likely that livestock are not the primary grazers of Graham's or White River beardtongues. High rates of herbivory occur from invertebrates,

rabbits, cattle, deer, and sheep, and herbivory results in reduced fruit and seed production (Dodge and Yates 2011, pp. 7, 9). In particular, tiger moth caterpillars (possibly *Arctia caca utahensis*) have been identified foraging on Graham's beardtongue plants (Dodge and Yates 2011; Tepedino 2012).

At one study site, herbivory rates (measured by the number of plants browsed) were as high as 68 percent, but fluctuated greatly (Dodge and Yates 2011, entire). Herbivory appeared to decrease at times due to delayed plant development during cool, wet springs (Dodge and Yates 2011, pp. 10–11).

Despite high levels of herbivory, the monitored populations were mostly stable across 9 years (McCaffery 2013a, p. 4). Presumably, beardtongues would be adapted to herbivory by native grazers, which may explain why monitored populations continue to remain stable despite high levels of herbivory.

Grazing occurs throughout the range of Graham's and White River beardtongues. Approximately 52 percent of all known Graham's beardtongue plants and 61 percent of all White River beardtongue plants occur in 19 grazing allotments on BLM lands. Seasons of use vary considerably, with most allotments grazed over the winter (from November or December to April), although some allotments are grazed in the spring and summer (BLM 2008c, pp. J1–4). Grazing in the spring and summer are more likely to directly impact beardtongue individuals than grazing in the winter. Most White River beardtongue plants occur within six allotments: four sheep allotments with a season of use from October to May, one sheep allotment (Raven Ridge in Colorado) grazed from November to February, and one cattle allotment with season of use from April to June and October to February (BLM 2008c, pp. J1–4). Sheep are more likely to graze on forbs than cattle (Cutler 2011, entire), thus beardtongue individuals within sheep allotments are more likely to be grazed than those in cattle allotments. Sheep grazing can result in the removal of inflorescences of Graham's beardtongue, thereby preventing reproduction from occurring (Reisor 2014b; p. 2). Overall, grazing pressure may have less of an impact on the beardtongues now than it has in the past—in the past decade, BLM has reduced the number of grazing sheep by half on many of the allotments (Cutler 2011, entire). Grazing also likely occurs across areas owned by other landowners, although we do not have data on grazing on these other lands.

Besides impacts from grazing, which we do not find is negatively impacting Graham's or White River beardtongue at the species level, domestic livestock can impact rare and native plants by trampling them (71 FR 3158, January 19, 2006). We believe one population of Graham's beardtongue was eradicated by livestock trampling (Neese and Smith 1982, p. 66). Winter sheep grazing is the principal use across the range of White River beardtongue habitat, where sheep trailing (walking) likely results in damage or loss of plants (Franklin 1995, p. 6; UNHP 2012, entire). It is likely that some individuals of both beardtongue species, and particularly White River

beardtongue as it tends to grow on slightly steeper slopes (see *Species Information*, "Habitat" for both beardtongues above), are afforded some protection from trampling by cattle, as cattle generally avoid steep slopes. However, this characteristic would not prevent trampling by sheep, which are not deterred by steep slopes.

Livestock grazing can negatively impact native plants indirectly through habitat degradation or by influencing plant community composition. Across the Colorado Plateau, livestock trampling and trailing breaks and damages biological soil crusts (Belnap and Gillette 1997, entire); alters plant community composition (Cole *et al.* 1997, entire); spreads and encourages weed seed establishment (Davies and Sheley 2007, p. 179); increases dust emissions (Neff *et al.* 2008, entire); and compacts soils, affecting water infiltration, soil porosity, and root development (Castellano and Valone 2007, entire). Crusts are not known to be a major component of the soils that Graham's and White River beardtongues inhabit, but livestock likely have altered the physical features of the plants' habitats. Although the best available data do not indicate how livestock grazing has indirectly impacted Graham's beardtongue or White River beardtongue habitat, the invasive species cheatgrass, purple mustard, halogeton, and prickly Russian thistle have been documented growing with both beardtongues (see *Invasive Weeds*, below) (Fitts and Fitts 2009, p. 23; CNHP 2012, entire; Service 2012a, entire; UNHP 2012, entire). We assume that grazing has caused ecological changes, including nonnative weed invasion and other physical changes (e.g., loss of biological soil crusts), within beardtongue habitats (Mack and Thompson 1982, entire; Cole *et al.* 1997, entire). We do not know the extent and severity of these changes.

In summary, herbivory and trampling from grazing on some locations of Graham's and White River beardtongues appear to be severe during some years, and it is likely that similar impacts occur across the ranges of the species. The documented effects of herbivory and trampling on Graham's and White River beardtongues to date are limited to a reduction in reproductive output in some years at specific sites and the possible loss of one historical population, rather than widespread impacts on habitat or population-level impacts on the species. Despite high levels of herbivory, monitored populations appear to be stable. At present, we find that both species have sufficient resiliency, redundancy, and

representation to recover from existing grazing and trampling impacts, and we do not consider grazing to be a threat to these species by itself (see *Cumulative Effects from All Factors*, below, for more information).

2014 CA protections—The 2014 CA provides conservation measures to address the effects of livestock grazing on both species wherever they occur locally. The conservation team will develop and implement a monitoring plan to detect impacts to Graham's and White River beardtongues from livestock grazing. Where impacts are detected, BLM will adjust grazing regimes or take other measures to reduce these impacts. BLM can adjust grazing regimes by changing the season of use to ensure plants are not grazed during the growing period, reduce the number of livestock, rest and rotate pastures, and avoid suitable areas within pastures. This conservation measure will not only provide us with better information about the effects of livestock grazing, but it will also employ conservation measures at specific species occurrences where livestock grazing may be affecting the species.

Unauthorized Collection

In our 2013 proposed listing rule (71 FR 3158, January 19, 2006), we determined that unauthorized collection was not a threat to the species. Graham's beardtongue is a unique and charismatic species that is prized by collectors and, at least at one point in time, was available commercially online (71 FR 3158, January 19, 2006). However, we are not aware of any recent attempts to collect this species without proper authorizations. Since our 2013 proposed rule (78 FR 47590), we have no new information about the potential threat of unauthorized collection. Therefore, we do not consider unauthorized collection a threat to either beardtongue species.

Off-Highway Vehicle Use

In our 2013 proposed listing rule, we found that the use of off-highway or off-road vehicles (OHVs) was not a threat to either beardtongue species. The use of OHVs may result in direct loss or damage to plants and their habitat through soil compaction, increased erosion, invasion of noxious weeds, and disturbance to pollinators and their habitat (Eckert *et al.* 1979, entire; Lovich and Bainbridge 1999, p. 316; Ouren *et al.* 2007, entire; BLM 2008b, pp. 4–94; Wilson *et al.* 2009, p. 1). However, to date, little OHV use has occurred within the ranges of Graham's beardtongue and White River beardtongue. For example, unauthorized OHV use was observed at only four locations within White River

beardtongue occupied habitat 10 to 20 years ago (UNHP 2012, entire). Federal and industry personnel were increasingly using OHVs in oil and gas field surveys and site location developments prior to 2008. However, since 2008, the revised Vernal Field Office RMP limits all vehicles to designated routes (BLM 2008c, p. 46). This protective measure provides conservation benefits within the habitat of Graham's and White River beardtongues. We do not have any additional information regarding impacts to the species from off-highway vehicle use since our 2013 proposal (78 FR 47590). Given the low levels of documented unauthorized OHV use and the protections provided by the BLM Vernal RMP, we do not consider OHV use a threat to either beardtongue species.

2014 CA protections—In addition to the protective measures (i.e., limited to designated routes) provided in the Vernal RMP, the 2014 CA specifies that BLM will identify areas for closure or limited use as needed to protect the species through their travel management process. On non-Federal lands, landowners will attempt to keep OHV traffic away from designated conservation areas. These measures will help to prevent OHV use from becoming a threat to the species in the future.

Road Maintenance and Construction

In our 2013 proposed listing rule we found that road maintenance and construction was not a threat to Graham's or White River beardtongues. Roads that cross through rare plant habitat can destroy habitat and populations, increase road dust, and disturb pollinators (Trombulak and Frissell 2000, entire). We consider this issue separately from roads created for oil and gas development (see Energy Exploration and Development, above), although the effects are the same.

Many unpaved county roads cross through Graham's and White River beardtongue habitat, and most of these roads have existed for decades. Plants located near unpaved roads are prone to the effects of dust, fragmentation, and pollinator disturbance (see Energy Exploration and Development, above, for a thorough discussion of road effects). Two long-term monitoring plots for Graham's and White River beardtongues are immediately adjacent to unpaved roads, and these populations were stable over nine years of the study (Dodge and Yates 2011, pp. 9, 12; McCaffery 2013a, pp. 18–19). However, one monitoring plot of White River beardtongue produces fewer flowers and fruits than other sites of White River

beardtongue, potentially because of increased disturbance due to the nearby road (Dodge and Yates 2011, p. 12).

Conflicts can also arise from new paved roads or road upgrades, as described below. For example, in 2012, Seep Ridge Road, a formerly unpaved county road crossing through occupied Graham's beardtongue habitat, was realigned and paved. At least 322 individuals were within 91.4 m (300 ft) of the proposed right-of-way, and the project resulted in direct impacts to at least 31 Graham's beardtongue individuals that were transplanted out of the widened road right-of-way, but did not survive (Reisor 2013, entire; Roe 2014, pers. comm.). The paving of Seep Ridge Road reduced the impacts of fugitive dust, but the widened road corridor directly decreased the number of plants on the east side of the road and may impede pollinator movement, leading to this population of Graham's beardtongue becoming more isolated.

In summary, road maintenance and construction can destroy habitat and fragment populations, but this impact is site-specific and does not occur across the entire range of either species. We are not aware of other road construction or maintenance projects that have occurred, or are proposed to occur, in areas where they would impact Graham's beardtongue or White River beardtongue. Therefore, we do not consider road maintenance and construction to be a threat to either beardtongue species.

2014 CA protections—The 2014 CA designated conservation areas for both beardtongue species. Within designated conservation areas, surface disturbance will be limited to 5 percent new disturbance where Graham's beardtongue occurs and 2.5 percent new disturbance in areas occupied by White River beardtongue. In addition, disturbance such as road construction will avoid plants by 91.4 m (300 ft) within conservation areas and on BLM lands. These measures will help prevent road construction and maintenance from becoming threats to the species in the future.

Wildfire

In our 2013 proposed listing rule we found wildfire to be a contributor to cumulative threats to the species, but not to be a threat by itself (see Cumulative Effects from All Factors, below). In 2012, the Wolf Den Fire, believed to be started by dry lightning, burned 8,112 ha (20,046 ac) in Uintah County, including 394 ha (974 ac), or approximately 1.5 percent, of the area within 700 m (2,297 ft) of known points of Graham's beardtongue and

approximately 563 known plants (1.4 percent of the total known number of plants). No individuals of White River beardtongue were affected by this fire. Fires do not occur frequently in Graham's beardtongue or White River beardtongue habitat, but fire frequency and intensity is likely to increase with increased invasive weeds and climate change (see Invasive Weeds, Climate Change, and Cumulative Effects from All Factors, below, for more information). In addition, we do not yet know how these species respond to fire. It is likely that with patchy, low-intensity burns they would be able to resprout from their roots, which we have documented in the field for Graham's beardtongue (Brunson 2012, entire). Overall, we do not consider wildfire alone to be a threat to either species.

2014 CA protections—The conservation team will provide input into wildfire planning and post-wildfire actions in designated conservation areas. This measure will help to prevent unnecessary impacts to the species from pre- and post-planning and mitigation of wildfire activities.

Invasive Weeds

In our 2013 proposed listing rule we found invasive weeds to be a contributor to cumulative threats to the species, but not to be a threat by itself (Cumulative Effects from All Factors, below). Cheatgrass, halogeton, prickly Russian thistle, and purple mustard occur in Graham's beardtongue habitat (71 FR 3158, January 19, 2006; Service 2012c, entire), and may be extensive at site-specific locations (Malone 2014, p. 2.). In addition, invasive weeds are numerous in the habitat and plant communities immediately adjacent to beardtongue species habitat, most notably in disturbed areas (for example, along roads and well pads) (Service 2012c, entire).

The spread of nonnative, invasive species is considered the second largest threat to imperiled plants in the United States (Wilcove *et al.* 1998, p. 2). Invasive plants—specifically exotic annuals—negatively affect native vegetation, including rare plants. One of the most substantial effects is the change in vegetation fuel properties that, in turn, alters fire frequency, intensity, extent, type, and seasonality (Menakis *et al.* 2003, p. 282; Brooks *et al.* 2004, entire; McKenzie *et al.* 2004, entire). Shortened fire return intervals make it difficult for native plants to reestablish or compete with invasive plants (D'Antonio and Vitousek 1992, pp. 68–77). Invasive weeds can exclude native plants and alter pollinator

behaviors (D'Antonio and Vitousek 1992, pp. 68–77; DiTomaso 2000, p. 257; Mooney and Cleland 2001, pp. 74–75; Traveset and Richardson 2006, pp. 211–213). For example, cheatgrass outcompetes native species for soil, nutrients, and water (Melgoza *et al.* 1990, pp. 9–10; Aguirre and Johnson 1991, pp. 352–353).

Cheatgrass is a particularly problematic nonnative, invasive annual grass in the Intermountain West and, as discussed above, has been documented in Graham's and White River beardtongue habitat. If already present in the vegetative community, cheatgrass increases in abundance after a wildfire, increasing the chance for more frequent fires (D'Antonio and Vitousek 1992, pp. 74–75). In addition, cheatgrass invades areas in response to surface disturbances (Hobbs 1989, pp. 389–398; Rejmanek 1989, pp. 381–383; Hobbs and Huenneke 1992, pp. 324–330; Evans *et al.* 2001, p. 1,308). Cheatgrass is likely to increase due to climate change because invasive annuals increase biomass and seed production at elevated levels of carbon dioxide (Mayeaux *et al.* 1994, p. 98; Smith *et al.* 2000, pp. 80–81; Ziska *et al.* 2005, p. 1,328).

Overall, invasive species are present but not extensive across most of the beardtongues' occupied habitats. Therefore, we do not currently consider invasive weeds alone to be a threat to either beardtongue species, but we later evaluate cumulative effects with energy development and climate change (see Cumulative Effects from All Factors, below for more information).

2014 CA protections—The conservation team committed to developing, funding, and implementing a weed management plan in designated conservation areas; the plan will include prevention measures, surveys to detect invasion, treatment options, and monitoring plans. The conservation team will develop annual work plans adapted to best prevent, detect, and manage invasive weeds. When enacted, this conservation measure will reduce the threats posed by invasive weeds to both beardtongue species when considered cumulatively with other impacts.

Small Population Size

In our 2013 proposed listing rule we found small population size to be a contributor to cumulative threats to the species, but not to be a threat by itself (Cumulative Effects from All Factors, below). We lack complete information on the population genetics of Graham's and White River beardtongues. Preliminary genetic analysis shows that both beardtongues have less diversity

than more common beardtongue species that have overlapping ranges (Arft unpublished report 2002). As previously described (see Background, “Biology” for both plants, above), both species have mixed mating systems and are thus capable of producing seed through self-fertilization or cross-pollination. However, the highest number of seeds and fruits are produced when flowers are cross-pollinated (Lewinsohn and Tepedino 2007, pp. 233–234; Dodge and Yates 2009, pp. 9–11). Increased disturbance and habitat fragmentation resulting in smaller population sizes could negatively impact both species because there would be fewer plants available for cross-pollination.

Small populations and species with limited distributions are vulnerable to relatively minor environmental disturbances (Given 1994, pp. 66–67). Small populations also are at an increased risk of extinction due to the potential for inbreeding depression, loss of genetic diversity, and lower sexual reproduction rates (Ellstrand and Elam 1993, entire; Wilcock and Neiland 2002, p. 275). Lower genetic diversity may, in turn, lead to even smaller populations by decreasing the species' ability to adapt, thereby increasing the probability of population extinction (Barrett and Kohn 1991, pp. 4, 28; Newman and Pilson 1997, p. 360).

Populations of either species with fewer than 150 individuals are more prone to extinction from stochastic events than larger populations (McCaffery 2013b, p. 1). Overall, it appears that Graham's beardtongue has many small populations scattered across its range, although the largest population (population 19.) contains more than 11,000 plants. Of the 24 populations of Graham's beardtongue, approximately 13 contain fewer than 150 known plants. That means more than half the known populations are more prone to extinction from stochastic events due to small population size. However, these populations account for only 1.4 percent of the total known number of plants of Graham's beardtongue. In addition, the species' widespread distribution may contribute to Graham's beardtongue's overall viability and potential resilience. For example, small-scale stochastic events, such as the erosion of a hillside during a flood event, will likely impact only a single population or a portion of that population. Even larger, landscape-level events such as wildfires are not likely to impact the species as a whole (see Wildfire, above). We do not find that small population size is a species-level concern for Graham's beardtongue (see

Cumulative Effects from All Factors, below, for additional information).

White River beardtongue has only 8 populations, and 2 of these have fewer than 150 individual plants. These two smaller populations account for less than 1 percent of the total species' population. However, large areas of suitable habitat remain unsurveyed, so this species may be more widely distributed, and populations are likely to have different numbers of plants than presented here. Overall, this species' range is much smaller than that of Graham's beardtongue, and thus we conclude that White River beardtongue may be more prone to extinction from landscape-level events. However, in the absence of information identifying threats to the species and linking those threats to the rarity of the species, we do not consider small population size alone to be a threat. A species that has always been rare, yet continues to survive, could be well equipped to continue to exist into the future. White River beardtongue likely fits this category, so persistence may be likely despite its small population size. Many naturally rare species have persisted for long periods within small geographic areas, and many naturally rare species exhibit traits that allow them to persist, despite their small population sizes. Consequently, the fact that a species is rare does not necessarily indicate that it may be in danger of extinction in the future.

Based on Graham's and White River beardtongues' current population numbers and preliminary demographic analyses showing that monitored sites are, for the most part, stable (McCaffery 2013a, entire), we conclude that small population size is not currently a threat to these species. In addition, a population viability analysis for both species indicates a high likelihood of persistence over the next 50 years for populations with more than 116 plants for Graham's beardtongue and 259 plants for White River beardtongue. However, we further evaluated cumulative effects associated with energy development, grazing, invasive species, and climate change (see Cumulative Effects from All Factors, below).

2014 CA protections—The designation of conservation areas protect 64 and 76 percent of the populations of Graham's and White River beardtongues respectively. An additional 4% of Graham's beardtongue population will be protected by spatial buffers outside of conservation areas on BLM lands. This conservation measure is consistent with BLM protections for the species since 2007. Conservation

areas include subpopulations that are large enough (>116 Graham's beardtongue and >259 White River beardtongue) that they have a low chance of extinction over the next 50 years (McCaffrey 2013a). The conservation areas also protect many of the smaller populations, ensuring population connectivity. In addition, the conservation team will plan and implement a study to better understand the genetic representation of White River beardtongue and how it is related with other closely related beardtongue species. The protections in the 2014 CA prevent small population size from becoming a threat to either beardtongue species.

Climate Change

In our 2013 proposed rule we found climate change to be a contributor to cumulative threats to the species, but not to be a threat by itself (Cumulative Effects from All Factors, below). Our analyses under the Act include consideration of ongoing and projected changes in climate. The terms "climate" and "climate change" are defined by the Intergovernmental Panel on Climate Change (IPCC). "Climate" refers to the mean and variability of different types of weather conditions over time, with 30 years being a typical period for such measurements, although shorter or longer periods also may be used (IPCC 2007, p. 78). The term "climate change" thus refers to a change in the mean or variability of one or more measures of climate (e.g., temperature or precipitation) that persists for an extended period, typically decades or longer, whether the change is due to natural variability, human activity, or both (IPCC 2007, p. 78). Various types of changes in climate can have direct or indirect effects on species. These effects may be positive, neutral, or negative and they may change over time, depending on the species and other relevant considerations, such as the effects of interactions of climate with other variables (e.g., habitat fragmentation) (IPCC 2007, pp. 8–19). In our analyses, we use our expert judgment to weigh relevant information, including uncertainty, in our consideration of various aspects of climate change.

Climate change is potentially impacting Graham's and White River beardtongues now, and could continue to impact these species into the future. Over the last 50 years, average temperatures have increased in the Northern Hemisphere, and extreme weather events have changed in frequency or intensity, including fewer cold days and nights, fewer frosts, more heat waves, and more hot days and

nights (IPCC 2007, p. 30). In the southwestern United States, average temperatures increased approximately 1.5 degrees Fahrenheit (°F) compared to a 1960 to 1979 baseline (Karl 2009, p. 129). Climate modeling is not currently forecasting at a level of detail at which we can predict the amount of temperature and precipitation change precisely within the limited ranges of these two beardtongue species. Therefore, we generally address what could happen under current climate projections based upon what we know about the biology of these two species.

Climate changes will continue as hot extremes, heat waves, and heavy precipitation will increase in frequency, with the Southwest experiencing the greatest temperature increase in the continental United States (Karl 2009, p. 129). Annual mean precipitation levels are expected to decrease in western North America and especially the southwestern States by mid-century (IPCC 2007, p. 8; Seager *et al.* 2007 p. 1,181), with a predicted 10- to 30-percent decrease in precipitation in mid-latitude western North America by the year 2050 (Milly *et al.* 2005, p. 1). These changes are likely to increase drought in the areas where Graham's and White River beardtongues grow.

We do not have a clear understanding of how Graham's and White River beardtongues respond to precipitation changes, although generally plant numbers decrease during drought years and recover in subsequent seasons that are less dry. Graham's beardtongue may not respond as quickly as White River beardtongue to increased winter and spring moisture immediately preceding the growing season (Lewinsohn and Tepedino 2007, pp. 12–13). In addition, Graham's beardtongue flowering is sporadic and may be responding to environmental factors that we have not been able to measure in the field, such as precipitation. Graham's beardtongue may need more than one year of normal precipitation to recover from prolonged drought (Lewinsohn 2005, p. 13), although this hypothesis has not been tested. Conversely, current analyses indicate that there is no association between regional precipitation patterns and population demographics (McCaffrey 2013a p. 16), although regional weather stations used in the analyses are not likely to pick up the site-specific precipitation that is more likely to influence these species' vital rates.

That these beardtongues are adapted to living on such hot and dry patches of soils (even more so than other native species in the same area) may mean they are better adapted to withstand

stochastic events such as drought. However, increased intensity and frequency of droughts may offer Graham's and White River beardtongues populations fewer chances to recover and may lead to a decline in both species. Some estimate that approximately 20 to 30 percent of plant and animal species are at increased risk of extinction if increases in global average temperature exceed 2.7 to 4.5 °F (1.5 to 2.5 °C) (IPCC 2007, p. 48). By the end of this century, temperatures are expected to exceed this range by warming a total of 4 to 10 °F (2 to 5 °C) in the Southwest (Karl 2009, p. 129).

Accelerating rates of climate change of the past two or three decades indicate that the extension of species' geographic range boundaries toward the poles or to higher elevations by progressive establishment of new local populations will become increasingly apparent in the relatively short term (Hughes 2005, p. 60). The limited range of oil shale substrate that Graham's and White River beardtongues inhabit could limit the ability of these species to adapt to changes in climatic conditions by progressive establishment of new populations. However, some experts believe that it may be possible for these species to move to other aspects within their habitat in order to adapt to a changing climate (Service 2012c, entire). For example, Graham's beardtongue is typically observed on west- or southwest-facing slopes (see *Species Information*, "Habitat" for Graham's beardtongue, above). White River beardtongue exhibits a similar characteristic, although this species is more evenly distributed on different slope aspects (see *Species Information*, "Habitat" for White River beardtongue, above). It may be possible for these species to gradually move to cooler and wetter slope aspects (for example, north-facing hillsides) within oil shale soils in response to a hotter drier climate (Service 2012c, entire), but only if these types of habitat are within reasonable seed-dispersal distances and only if these habitats remain intact with increasing oil and gas development.

In summary, climate change is affecting and will affect temperature and precipitation events in the future. We expect that Graham's and White River beardtongues, like other narrow endemics, may be negatively affected by climate change-related drought. However, the scope of any negative effects (i.e., whether they would rise to a level that threatens the species) is unknown and mostly speculative at this time. Current data are not reliable enough at the local level for us to draw conclusions regarding the impacts of

climate change as a threat to Graham's and White River beardtongues. However, we further evaluate the potential cumulative effects associated with energy development, invasive species, and small population size (see Cumulative Effects from All Factors, below).

2014 CA protections—Since we do not fully understand either Graham's or White River beardtongues' responses to climate change, the conservation team, depending on funding, will install weather monitoring equipment adjacent to long-term monitoring sites to collect much needed climate data. The data collected from weather monitoring will be correlated with demography data to determine basic species responses to climate patterns. This information will help the conservation team understand how to better craft conservation measures to address impacts from climate change. In the interim, designated conservation areas provide 21,106 ha (44,373 ac) of protected habitats for Graham's and White River beardtongues (see Ongoing and Future Conservation Efforts).

Inadequacy of Existing Regulatory Mechanisms

In our 2013 proposed rule, we found existing regulatory mechanisms to be inadequate to protect Graham's and White River beardtongues from the threats we had identified.

Federal

Within Colorado, the Raven Ridge Area of Critical Environmental Concern (ACEC) was established in 1997, in part, to protect candidate and BLM sensitive plant species, including Graham's and White River beardtongues (BLM 1985, p. 2, BLM 1997, p. 2–17). The Federal Land Policy and Management Act (FLPMA) (43 U.S.C. 1701 *et seq.*) defines ACECs as “areas within the public lands where special management attention is required . . . to protect and prevent irreparable damage to important historic, cultural, or scenic values, fish and wildlife resources or other natural systems or processes, or to protect life and safety from natural hazards” (Sec. 103(a)). Designation as an ACEC recognizes an area as possessing relevant and important values that would be at risk without special management attention (BLM 2008b, p. 4–426). To protect listed and candidate species including the beardtongues, the Raven Ridge ACEC restricts motorized travel to existing roads and trails and includes a no surface occupancy (NSO) stipulation for new oil and gas leases within the ACEC (BLM 1997, pp. 2–19, 2–44). The NSO designation prohibits

long-term use or occupancy of the land surface for fluid mineral exploration or development to protect special resource values (BLM 2008c, p. 38). However, NSO stipulations do not apply to valid existing rights (BLM 1997, p. 2–31), which account for 14 and 11 percent of the total known populations for Graham's and White River beardtongues, respectively.

Not quite half of all known Graham's beardtongue plants in Colorado occur within the Raven Ridge ACEC (37 of 81 or 46 percent). About 28 percent (439 of 1,579) of the known White River beardtongue plants in Colorado also occur within the Raven Ridge ACEC. We expect the NSO stipulation will continue to provide sufficient protection to the plants in the ACEC. Twenty-one percent of the Raven Ridge ACEC is currently leased, and the NSO stipulations for future leasing are in effect for this entire area; however, conditions of approval such as avoidance of plants by 300 ft can be identified and incorporated through the NEPA process. An additional 30 percent of the Raven Ridge ACEC was proposed for leasing in 2013, but the lease sale is now deferred for further analysis (BLM 2013b, entire). To date, no wells have been drilled or approved within the Raven Ridge ACEC (Service 2013, p. 12). There are no ACECs established for either Graham's beardtongue or White River beardtongue in Utah.

Both species are listed as BLM sensitive plants in Colorado and Utah, which affords them limited policy-level protection through the Special Status Species Management Policy Manual #6840, which forms the basis for special status species management on BLM lands (BLM 2008a, entire). Because both beardtongue species are considered BLM sensitive and candidate species under the Act, the BLM currently protects them as they would listed species. In addition, conservation measures for Graham's beardtongue from the 2007 CA incorporated by the Vernal Field Office include a 91-m (300-ft) setback from surface-disturbing activities (BLM 2008c, p. L–16).

As previously described (see Ongoing and Future Conservation Efforts), in 2007, a voluntary 5-year conservation agreement for Graham's beardtongue was signed by the Service, the BLM, and the Utah DNR. The agreement intended to create a program of conservation measures to address potential threats to Graham's beardtongue at the Federal, State, and local levels. Since the conservation agreement was signed, the BLM has funded surveys for both species, adding 4,000 new Graham's beardtongue points and 400 new White

River beardtongue points to our files. In addition, a long-term monitoring program on both species has been ongoing since 2004. However, BLM will not be able to retain Federal ownership of all occupied habitat, as recommended in the 2007 CA. The Utah Recreational Land Exchange Act of 2009 (Public Law 111–53, signed August 19, 2009) directed the exchange of lands within Grand, San Juan, and Uintah Counties, Utah, between the BLM and SITLA. Several of the parcels that were transferred to SITLA include 883 (2 percent) known individual Graham's beardtongue plants within populations 13 and 16, and the lands occur in areas of high potential energy development (see Energy Exploration and Development, above). The land exchange was finalized on May 8, 2014 (SITLA 2014).

The FLPMA requires the BLM to develop and revise land-use plans when appropriate (43 U.S.C. 1712(a)). The BLM developed a new resource management plan (RMP) for the Vernal Field Office in 2008 to consolidate existing land-use plans and balance use and protection of resources (BLM 2008c, pp. 1–2). Through the Vernal Field Office RMP, the BLM commits to conserve and recover all special status species, including candidate species (BLM 2008c, p. 129). However, the RMP special status species goals and objectives as previously drafted were not adequate to ensure that all Federal actions avoid impacts to Graham's beardtongue or White River beardtongue. Conservation measures previously implemented by the BLM have not fully prevented impacts (for example, well pad development or road maintenance and construction in occupied habitat as discussed previously in Energy Exploration and Development, and Road Maintenance and Construction) to Graham's beardtongue or White River beardtongue.

2014 CA protections—The 2014 CA provides for additional protection of the species because BLM will establish conservation areas where new surface-disturbing activities will be limited to 5 percent for Graham's beardtongue and 2.5 percent for White River beardtongue; avoid Graham's and White River beardtongues from surface-disturbing activities by 91.4 m (300 ft); and mitigate impacts when plants cannot be avoided by 91.4 m (300 ft). The BLM will implement the measures of the 2014 CA through incorporation of the conservation measures in permitting processes and policy. BLM will incorporate the conservation measures during its next RMP planning process.

During oil and gas development activities that have occurred to date, the BLM minimized some impacts to Graham's beardtongue and its habitat through incorporation of conservation measures from the 2007 Conservation Agreement. Conservation measures include moving well pad and pipeline locations to avoid direct impacts to the species. These measures minimize direct impacts to the species, particularly at the current low rates of development that have occurred in the habitat.

We conclude that existing and future conservation measures achieved through the 2014 CA, including the creation of conservation areas, limiting new surface disturbances, and applying a 91-m (300-ft) avoidance measure, are sufficient to protect these species.

State

No State laws or regulations specifically protect rare plant species in Utah or Colorado. Utah law prevents only the harvest or transport of native vegetation without proof of ownership or written permission of the landowner or managing State or Federal agency (Utah Code 78B chapter 8 Section 602). Approximately 27 and 10 percent of all known plants of Graham's and White River beardtongues, respectively, occur on State land. After the land exchange as described above, about 29 percent of all known Graham's beardtongue plants will be located on State lands. We do not know of any White River beardtongues occurring on lands identified for exchange.

2014 CA protections—As a signatory to the 2014 CA, SITLA, and UDWR are establishing 794 ha (1,961 ac) of State lands as conservation areas for Graham's and White River beardtongues. These conservation areas contain 4.4 percent of the total population of Graham's beardtongue and 1.4 percent of the total population of White River beardtongue. As previously described, within these conservation areas additional surface disturbance will be limited to 5 percent for conservation areas designated for Graham's beardtongue and 2.5 percent for conservation areas for White River beardtongue, and surface disturbance will avoid plants by 91.4 m (300 ft) or mitigate unavoidable impacts. The SITLA will establish these conservation areas with associated conservation measures through a regulation, director's order, or joint lease stipulation. With these regulatory mechanisms in place both beardtongues species are afforded some additional protection on State lands.

Local

As stated above, approximately 21 and 28 percent of all known plants of Graham's and White River beardtongues, respectively, occur on private lands, and the majority of these are in Uintah County, Utah.

2014 CA protections—Through the 2014 CA, Uintah County, Utah, will enact a zoning ordinance that would designate 2,787 acres of conservation areas that protect 12 percent (4,764 plants) of Graham's beardtongue and 13 percent (1,574) of White River beardtongue on private lands. The ordinance would establish conservation areas and would adopt the surface-disturbance limits and buffers on private lands as described in Table 4. The enactment of a zoning ordinance by Uintah County provides additional regulatory protections to a significant portion of both beardtongue populations on private lands.

Summary of Inadequacy of Existing Regulatory Mechanisms

In summary, we find that both species will be afforded protection through the implementation of the 2014 CA and its establishment and management of conservation areas that protect 64 percent of the population of Graham's and 76 percent of the population of White River beardtongues. The BLM will apply necessary regulatory provisions through permitting and conditions of approval. Uintah County and SITLA will utilize zoning ordinances and regulations, respectively, to implement the conservation commitments of the 2014 CA. Because of these additional conservation measures and implementing regulations associated with the 2014 CA, we conclude that existing regulatory mechanisms are adequate to protect both species.

Cumulative Effects From All Factors

In our 2013 proposed rule, we concluded that the cumulative effects of increased energy development, livestock grazing, invasive weeds, small population sizes, and climate change were a threat to the two beardtongue species. The combination of these factors could increase the vulnerability of these species. Smaller populations, as discussed above (see Small Population Size), are more prone to extinction, and these smaller populations could experience more severe effects of other factors. For example, incremental increases in habitat alteration and fragmentation from increased energy development (including oil shale, tar sands, and traditional oil and gas) could

increase weed invasion and fugitive dust, as well as increase the severity of impacts from other factors such as grazing, as grazers become more concentrated into undisturbed areas, and road maintenance, as more roads are constructed.

Climate change is likely to augment the ability of invasive, nonnative species to outcompete native plant species and also reduce the ability of native plant species to recover in response to perturbations. Climate change may also change the effects of grazing events from native grazers to the extent that reproduction of either beardtongue species is hindered so that populations are no longer resilient. This scenario underscores the need to protect not only the associated plant communities within Graham's and White River beardtongue habitat, but those immediately adjacent to beardtongue habitat (Service 2012c, entire). Measures such as implementing a 300-ft buffer from disturbance, connecting populations by protecting areas between occurrences, and ensuring protection measures are spread across the range of the species will help to ensure resiliency of both species.

2014 CA protections—The 2014 CA addresses the threat from energy development, as well as each of the individual factors that contribute to the cumulative threats to the species from energy development (see Energy Exploration and Development), livestock grazing (see Grazing and Trampling), invasive weeds (see Invasive Weeds), small population size (see Small Population Size), and climate change (Climate Change). The 2014 CA provides protection to Graham's and White River beardtongues and their associated plant and pollinator communities at a landscape level through the establishment and management of the conservation areas that protect both occupied and suitable habitat. The conservation area boundaries were drawn to connect populations and include adjacent natural communities. The 300-ft buffer from disturbance and limited surface disturbance helps to ensure that the disturbance within conservation areas is low enough to maintain the integrity of the natural community. In addition, both species are represented within conservation areas across their ranges as shown by units in Figure 3. Thus the conservation areas protect natural areas immediately adjacent to beardtongue habitat. The implementation, most notably of surface-disturbance caps and avoidance buffers, ensures the protection of individual plants, populations, and population

connectivity. In addition, the 2014 CA provides for monitoring and adaptive management associated with livestock grazing, invasive weeds, and climate change. These combined conservation approaches address the threats identified in the proposed rule independently and thus will prevent these threats from acting cumulatively.

Determination

As required by the Act, we considered the five factors in assessing whether the Graham's or White River beartongue meets the definition of a threatened or endangered species. We examined the best scientific and commercial information available regarding present and future threats to the species. Based on our review of the best available scientific and commercial information, we find that the current and future threats are not of sufficient imminence, intensity, or magnitude to indicate that either the Graham's or White River beartongue is in danger of extinction (endangered), or likely to become endangered within the foreseeable future (threatened), throughout all or a significant portion of its range. Therefore, Graham's and White River beartongues do not meet the definition of a threatened or endangered species, and we are withdrawing the proposed rules to list Graham's and White River beartongues as threatened species and designate critical habitat for these species. Our rationale for this finding is outlined below.

Graham's and White River beartongues have restricted ranges limited to a specific soil type, but where monitored their populations are stable. The existing numbers of individuals and populations are sufficient for these species to remain viable into the future. Further, the distribution of Graham's and White River beartongues encompasses and is representative of the known genetic diversity of both beartongue species, helping to support the species' resiliency to stochastic events.

In our proposed rule, we identified several threats that we expected to significantly impact the status of these species into the foreseeable future, which was based on the best available scientific and commercial information at that time. One of the threats to both beartongue species identified in the 2013 proposed rule was from energy development. We concluded that population stability of both species was likely to deteriorate as habitat loss and fragmentation from energy development, particularly oil shale and tar sands, was likely to be a threat to Graham's and White River beartongues

in the foreseeable future. Our conclusion was based on the extent and magnitude of energy development that is likely to happen in the foreseeable future and the lack of adequate measures to protect and conserve these species. Oil shale and tar sands overlap most of the known habitat of these species. Up to 79 and 90 percent of the total known populations of Graham's and White River beartongues could potentially be impacted with this type of development within the next few years, as Redleaf has secured all permits to begin work in 2014 (Redleaf 2014), and project construction for the Enfit project is planned to start in 2017 (BLM 2013e).

However, since that time, significant ongoing and new conservation efforts through the 2014 CA have reduced the magnitude of potential impacts in the future such that these species no longer meet the definition of a threatened or endangered species. The 2014 CA establishes conservation areas for both species on Federal, State, and private lands where surface disturbance will be limited to an additional 5 percent from the current baseline for Graham's beartongue and an additional 2.5 percent from the current baseline for White River beartongue and an avoidance buffer of 91.4 m (300 ft) from plants will be maintained, which is expected to protect the habitat of the species and their pollinators. On BLM lands, any surface disturbance occurring inside or outside of conservation areas will avoid Graham's beartongue or White River beartongue by 91.4 m (300 ft).

The conservation measures in the 2014 CA will protect 64 percent of the population of Graham's beartongue and 76 percent of the population of White River beartongue in conservation areas, maintaining the resiliency of both species so that they can better withstand cumulative impacts from invasive weeds, climate change, and small population size. Another 4 percent of the Graham's beartongue population will be protected outside of conservation areas on BLM lands by spatial buffers that will protect plants from surface-disturbing activities by 300 ft. This conservation measure is consistent with BLM protections for the species since 2007. In addition, threats from livestock grazing are addressed in the 2014 CA by monitoring livestock grazing to better understand and detect impacts to the species. Where impacts are detected, BLM will change the grazing regime or take other actions as necessary to reduce these impacts. This measure provides protection for both beartongue species

from livestock grazing. Additional measures include developing and implementing a weed management plan to prevent and control weed invasions and continued population monitoring. The conservation team will periodically review the status of Graham's and White River beartongue and make adjustments to conservation areas or conservation measures as appropriate to benefit and conserve the species. These measures will significantly reduce the threats to the species from energy development and the cumulative effects from energy development, livestock grazing, invasive weeds, climate change and small population size.

Certain conservation measures that are identified in the 2014 CA will be implemented via regulations, ordinance, and permitting. The signatory agencies that have implementation authority will put the regulatory controls in place to assure that these measures will be adequately implemented, e.g., BLM conditions of approval, County ordinances, SITLA regulations. In addition, the 2014 CA independently addresses and reduces the magnitude of each of the threats identified in the 2013 proposed rule. Addressing and reducing impacts from each threat individually will prevent them from acting cumulatively.

As summarized in the Ongoing and Future Conservation Efforts and PECE Analysis sections above, we have a high degree of certainty that the 2014 CA will be implemented (see Table 3) and effective. We have determined that the measures will be effective at eliminating or reducing threats to the species because they protect occupied and suitable habitat, provide habitat and additional management information to address the effects of energy development, livestock grazing, invasive weeds, climate change, small population size, and the inadequacy of regulatory mechanisms, and institute on-the-ground protections that better manage and protect habitat and address threats.

We have a high degree of certainty that the measures will be implemented because several of the conservation team partners have a track record of implementing conservation measures for the Graham's beartongue since 2007. Over approximately the past 6 years of implementation, BLM, Utah DNR, the Service, and Uintah County have implemented many of the conservation measures from the 2007 CA for Graham's beartongue, including species surveys, habitat modeling, avoidance of plants by surface-disturbing activities, incorporating the conservation measures from the

conservation agreement into the BLM Vernal Field Office RMP, examining the reproductive biology of the species, and conducting a demography study of the species. The 2014 CA has sufficient annual monitoring and reporting requirements to ensure that all of the conservation measures are implemented as planned, and are effective at removing threats to a substantial amount of Graham's and White River beardtongues and their habitat. The collaboration between the Service, Uintah County, Utah DWR, SITLA, PLPCO and BLM requires regular conservation team meetings and involvement of all parties in order to fully implement the 2014 CA, and a process has been agreed to among these entities to achieve this conservation objective. Based on the implementation of previous actions from several members of the conservation team, we have a high level of certainty that the conservation measures in the 2014 CA (for those measures not already begun), will be implemented and that they will be sufficiently effective.

In summary, we conclude that the conservation efforts in the 2014 CA have sufficient certainty of implementation and effectiveness that they can be relied upon in this final listing determination. Further, we conclude that conservation efforts have reduced or eliminated current and future threats to Graham's and White River beardtongues to the point that the species are no longer in danger of extinction now or in the foreseeable future.

The threat from energy development and especially oil shale development has been reduced by the conservation measures in the 2014 CA for the foreseeable future as oil shale development is expected to proceed slowly and avoid plants within established conservation areas over the next 15 years. Development of oil shale resources over the next 10–15 years will determine the intensity, magnitude, and long-term viability of this threat. Continued expansion of oil shale resources will depend on the industry's success over the next 10–15 years. Since we cannot predict the demand for energy and the viability of oil shale development beyond 15 years, the foreseeable future from the threat of energy development to Graham's and White River beardtongue from oil shale development is 10–15 years. The threat to the species from the cumulative impacts of energy development, grazing, invasive weeds, small population sizes, and climate change is also the same 10–15-year time period because energy development would be the leading threat to causing widespread landscape-

scale disturbance. Without the threat of energy development, the other threats do not rise to a level where they would act cumulatively, and thus these other impacts will not threaten Graham's and White River beardtongue in the foreseeable future. In addition, the 2014 CA addresses these threats over the foreseeable future and may be renewed after 15 years if successful at conserving the species.

Overall, since we expect the species to persist in their current distribution and to be protected from threats within 2014 CA designated conservation areas and on BLM lands, we conclude that they will have sufficient resiliency, redundancy, and representation to persist now and in the foreseeable future. Therefore, we are withdrawing our proposed rule to list Graham's and White River beardtongues as threatened species. Since these two species will not be listed under the Act, we are also withdrawing our proposed critical habitat rule as it is no longer applicable.

We will continue to monitor the status of both species through monitoring requirements in the 2014 CA, and to evaluate any additional information we receive. These monitoring requirements will not only inform us of the amount of disturbance from energy development, impacts to the species from livestock grazing, and amount of habitat occupied by invasive weeds within Graham's and White River beardtongues designated conservation areas, but will also help inform us of the status of Graham's and White River beardtongues population and stability. Additional information will continue to be accepted on all aspects of the species. We encourage interested parties, outside of those parties already signatories to the 2014 CA, to become involved in the conservation of the Graham's and White River beardtongues.

If at any time data indicate that protections under the Act may be warranted, for example, should we become aware of declining implementation of or participation in the 2014 CA, or noncompliance with the conservation measures, or if there are new threats or increasing stressors that rise to the level of a threat to either species, we will initiate listing procedures, including, if appropriate, emergency listing pursuant to section 4(b)(7) of the Act.

Significant Portion of the Range

Under the Act and our implementing regulations, a species may warrant listing if it is an endangered or a threatened species throughout all or a significant portion of its range. The Act defines "endangered species" as any

species which is "in danger of extinction throughout all or a significant portion of its range," and "threatened species" as any species which is "likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range." The term "species" includes "any subspecies of fish or wildlife or plants, and any distinct population segment [DPS] of any species of vertebrate fish or wildlife which interbreeds when mature." We published a final policy interpreting the phrase "Significant Portion of its Range" (SPR) (79 FR 37578). The final policy states that (1) if a species is found to be an endangered or a threatened species throughout a significant portion of its range, the entire species is listed as an endangered or a threatened species, respectively, and the Act's protections apply to all individuals of the species wherever found; (2) a portion of the range of a species is "significant" if the species is not currently an endangered or a threatened species throughout all of its range, but the portion's contribution to the viability of the species is so important that, without the members in that portion, the species would be in danger of extinction, or likely to become so in the foreseeable future, throughout all of its range; (3) the range of a species is considered to be the general geographical area within which that species can be found at the time FWS or NMFS makes any particular status determination; and (4) if a vertebrate species is an endangered or a threatened species throughout an SPR, and the population in that significant portion is a valid DPS, we will list the DPS rather than the entire taxonomic species or subspecies.

The SPR policy is applied to all status determinations, including analyses for the purposes of making listing, delisting, and reclassification determinations. The procedure for analyzing whether any portion is an SPR is similar, regardless of the type of status determination we are making. The first step in our analysis of the status of a species is to determine its status throughout all of its range. If we determine that the species is in danger of extinction, or likely to become so in the foreseeable future, throughout all of its range, we list the species as an endangered (or threatened) species and no SPR analysis will be required. If the species is neither an endangered nor a threatened species throughout all of its range, we determine whether the species is an endangered or a threatened species throughout a significant portion of its range. If it is, we list the species

as an endangered or a threatened species, respectively; if it is not, we conclude that listing the species is not warranted.

When we conduct an SPR analysis, we first identify any portions of the species' range that warrant further consideration. The range of a species can theoretically be divided into portions in an infinite number of ways. However, there is no purpose to analyzing portions of the range that are not reasonably likely to be significant and either an endangered or a threatened species. To identify only those portions that warrant further consideration, we determine whether there is substantial information indicating that (1) the portions may be significant and (2) the species may be in danger of extinction in those portions or likely to become so within the foreseeable future. We emphasize that answering these questions in the affirmative is not a determination that the species is an endangered or a threatened species throughout a significant portion of its range—rather, it is a step in determining whether a more detailed analysis of the issue is required. In practice, a key part of this analysis is whether the threats are geographically concentrated in some way. If the threats to the species are affecting it uniformly throughout its range, no portion is likely to warrant further consideration. Moreover, if any concentration of threats apply only to portions of the range that clearly do not meet the biologically based definition of “significant” (i.e., the loss of that portion clearly would not be expected to increase the vulnerability to extinction of the entire species), those portions will not warrant further consideration.

If we identify any portions that may be both (1) significant and (2) endangered or threatened, we engage in a more detailed analysis to determine whether these standards are indeed met. The identification of an SPR does not create a presumption, prejudgment, or other determination as to whether the species in that identified SPR is an endangered or a threatened species. We must go through a separate analysis to determine whether the species is an endangered or a threatened species in the SPR. To determine whether a species is an endangered or a threatened species throughout an SPR, we will use the same standards and methodology that we use to determine if a species is

an endangered or a threatened species throughout its range.

Depending on the biology of the species, its range, and the threats it faces, it may be more efficient to address the “significant” question first, or the status question first. Thus, if we determine that a portion of the range is not “significant,” we do not need to determine whether the species is an endangered or a threatened species there; if we determine that the species is not an endangered or a threatened species in a portion of its range, we do not need to determine if that portion is “significant.”

Our review determined that there are no concentrations of threats in any part of the ranges occupied by Graham's or White River beardtongues. In our 2013 proposed rule, we identified populations 19 and 20 of Graham's beardtongue (Figure 1) and the heart of White River beardtongue range (Population 3; Figure 2) as vulnerable due to ex-situ oil shale development. The majority of these populations occurs on private lands, and provides an important connectivity link between populations in Utah and Colorado. The 2014 CA addressed these concerns by providing protections for both species across their ranges, including protections on private lands within populations 19 and 20 for Graham's beardtongue and population 3 for White River beardtongue. Protections include the establishment of conservation areas that encompass 17,957 ha (44,373 ac) of occupied and suitable habitat, surface disturbance limits, detection surveys prior to project initiation, and avoidance of plants by 300 ft from surface-disturbing activities within conservation areas. Conservation areas will protect 64 percent of the known population of Graham's beardtongue across its range and 76 percent of the population of White River beardtongue across its range. In addition, on BLM lands Graham's and White River beardtongues will be avoided by 300 ft from surface-disturbing activities. These protections reduce the threats to the species that otherwise may have been considered geographically concentrated. With the development and implementation of the 2014 CA, we find no portions of these species' ranges where potential threats are significantly concentrated or are substantially greater than in other portions of their ranges. Therefore, we find that factors affecting each species

are essentially uniform throughout their ranges, indicating no portion of the range of the two species warrants further consideration of possible endangered or threatened status under the Act.

Conclusion

Our review of the best available scientific and commercial information indicates that with the development and implementation of the 2014 CA, neither Graham's beardtongue nor White River beardtongue is in danger of extinction (an endangered species), or likely to become endangered within the foreseeable future (a threatened species), throughout all or a significant portion of their ranges. Therefore, we find that listing Graham's beardtongue or White River beardtongue as endangered or threatened species under the Act is not warranted at this time.

We request that you submit any new information concerning the status of, or threats to, Graham's and White River beardtongues to our Utah Field Office (see **ADDRESSES** section) whenever it becomes available. New information will help us monitor these two plant species and encourage their conservation. If an emergency situation develops for either of these species, we will act to provide immediate protection.

References Cited

A complete list of all references cited in this document is available on the Internet at <http://www.regulations.gov> at Docket No. FWS-R6-ES-2013-0081 and Docket No. FWS-R6-ES-2013-0082, or upon request from the Field Supervisor, Utah Ecological Services Field Office (see **ADDRESSES** section).

Authors

The primary authors of this document are the staff members of the Utah Ecological Services Field Office (see **ADDRESSES**).

Authority

The authority for this action is the Endangered Species Act of 1979, as amended (16 U.S.C. 1531 *et seq.*).

Dated: July 22, 2014.

Stephen Guertin,

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

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49 CFR Part 571

Federal Motor Vehicle Safety Standards; Bus Rollover Structural Integrity,
Motorcoach Safety Plan; Proposed Rule

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety
Administration

49 CFR Part 571

[Docket No. NHTSA–2014–0085]

RIN 2127–AK96

Federal Motor Vehicle Safety
Standards; Bus Rollover Structural
Integrity, Motorcoach Safety Plan

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: NHTSA is issuing this NPRM to propose a new Federal motor vehicle safety standard to enhance the rollover structural integrity of certain types of large buses (generally, over-the-road buses (of any weight) and non-over-the-road buses with a gross vehicle weight rating (GVWR) greater than 11,793 kilograms (kg) (26,000 pounds (lb)). The agency is proposing performance requirements that new large buses of these types must meet in a test in which the vehicle is tipped over from an 800 millimeter (mm) raised platform onto a level ground surface. The performance requirements would ensure that these vehicles provide a sufficient level of survival space to restrained occupants in rollover crashes. The performance requirements would also ensure that seats and overhead luggage racks remain secured and window glazing attached to its mounting during and after a rollover crash, and would ensure that emergency exits remain closed during the rollover crash and operable after the crash.

This NPRM is among the rulemakings issued pursuant to NHTSA's 2007 Approach to Motorcoach Safety and DOT's Departmental Motorcoach Safety Action Plan. In addition, establishing roof strength and crush resistance requirements, to the extent warranted under the National Traffic and Motor Vehicle Safety Act, would fulfill a statutory provision of the Motorcoach Enhanced Safety Act of 2012 (incorporated and passed as part of the Moving Ahead for Progress in the 21st Century Act).

DATES: Comments must be received on or before October 6, 2014.

ADDRESSES: You may submit comments to the docket number identified in the heading of this document by any of the following methods:

- *Federal eRulemaking Portal:* go to <http://www.regulations.gov>. Follow the

online instructions for submitting comments.

- *Mail:* Docket Management Facility, M–30, U.S. Department of Transportation, West Building, Ground Floor, Rm. W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., between 9 a.m. and 5 p.m. Eastern Time, Monday through Friday, except Federal holidays.

- *Fax:* (202) 493–2251.

Regardless of how you submit your comments, please mention the docket number of this document.

You may also call the Docket at 202–366–9324.

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the Supplementary Information section of this document. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Privacy Act: Please see the Privacy Act heading under Rulemaking Analyses and Notices.

FOR FURTHER INFORMATION CONTACT: For non-legal issues, Ms. Shashi Kuppa, Office of Crashworthiness Standards (telephone: 202–366–3827) (fax: 202–493–2990). Ms. Kuppa's mailing address is National Highway Traffic Safety Administration, NVS–113, 1200 New Jersey Avenue SE., Washington, DC 20590.

For legal issues, Mr. Jesse Chang, Office of the Chief Counsel (telephone: 202–366–2992) (fax: 202–366–3820). Mr. Chang's mailing address is National Highway Traffic Safety Administration, NCC–112, 1200 New Jersey Avenue SE., Washington, DC 20590.

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I. Executive Summary

This rulemaking is part of both NHTSA and DOT's continual effort to improve safety in motorcoaches and other types of large buses. In 2007, NHTSA published its Approach to Motorcoach Safety describing NHTSA's comprehensive strategy to improve motorcoach safety.¹ The plan was developed to respond to several National Transportation Safety Board (NTSB) recommendations, and also to address several crashes that occurred after those recommendations were issued. In 2009, DOT issued a Departmental Motorcoach Safety Action Plan,² which outlined a Department-wide strategy to enhance motorcoach safety, addressing additional factors such as driver fatigue and operator maintenance issues.

NHTSA's Approach to Motorcoach Safety identified four specific areas where NHTSA could most effectively address open NTSB recommendations and potentially improve motorcoach safety. The four priority areas were: Reducing the risk of passenger ejection from the motorcoach, improving rollover structural integrity, enhancing emergency evacuation, and upgrading fire safety.

NHTSA has published a final rule (RIN 2127–AK56) on the first area detailed in NHTSA's Approach to Motorcoach Safety, requiring seat belts for each passenger seating position in: (a) All new over-the-road buses³; and (b) in new buses other than over-the-road buses, with a GVWR greater than 11,793 kg (26,000 lb).⁴ Today's NPRM

¹ See Docket No. NHTSA–2007–28793, *NHTSA's Approach to Motorcoach Safety*. In NHTSA's plan, "motorcoach" referred to inter-city transport buses.

² An update to the 2009 plan was published in December 2012, <http://www.fmcsa.dot.gov/safety-security/pcs/Motorcoach-Safety-Action-Plan.aspx>.

³ An over-the-road bus is a bus characterized by an elevated passenger deck located over a baggage compartment.

⁴ Some buses are excluded from this latter category, such as transit and school buses.

builds on the seat belt final rule by proposing to require those buses to meet increased structural integrity and other requirements to protect both restrained and unrestrained occupants in rollover crashes.

On July 6, 2012, the President signed the “Moving Ahead for Progress in the 21st Century Act” (MAP-21).⁵ MAP-21 incorporates the “Motorcoach Enhanced Safety Act of 2012” (Motorcoach Enhanced Safety Act) in Subtitle G (§§ 32701 *et seq.*) Among other matters, the Motorcoach Enhanced Safety Act requires DOT to “establish improved roof and roof support standards for motorcoaches that substantially improve the resistance of motorcoach roofs to deformation and intrusion to prevent serious occupant injury in rollover crashes involving motorcoaches” if such standards “meet the requirements and considerations set forth in subsections (a) and (b) of section 30111 of title 49, United States Code.”⁶ In addition, MAP-21⁷ directs DOT to consider “portal improvements to prevent partial and complete ejection of motorcoach passengers, including children.” Under MAP-21, “motorcoach” means an over-the-road bus, but does not include a bus used in public transportation provided by, or on behalf of, a public transportation agency, or a school bus.

We have issued this NPRM in furtherance of NHTSA’s goal to enhance the safety of all heavy buses used in intercity bus transportation, including over-the-road buses, which were the focus of the Motorcoach Enhanced Safety Act of MAP-21. Similar to the

seat belt rule, we are not proposing that this standard apply to school buses and urban transit buses.

Transportation by over-the-road buses (and other similar large buses) is an overall safe form of transportation. Over the ten year period between 2000 and 2009, there were 87 fatal crashes involving the large bus types covered by today’s proposed rule. These crashes resulted in 209 occupant fatalities (168 passenger and 41 driver fatalities). During this period, on average, 21 fatalities have occurred annually to occupants of these buses in crashes. Annually 17 of these fatalities were passengers and 4 were drivers. Nonetheless, given the high occupancy of these vehicles, a significant number of fatal or serious injuries can occur in a single crash. NHTSA tentatively believes that standards improving structural integrity and thereby side window glazing retention, issued pursuant to §§ 32703(b)–(b)(2) of MAP-21 and the National Traffic and Motor Vehicle Safety Act (“Motor Vehicle Safety Act”), would meet the need for safety. Among the 87 fatal crashes (involving the bus types covered by today’s proposal) that occurred from 2000–2009, data from NHTSA’s Fatality Analysis Reporting System (FARS) indicate that 32 were rollover crashes resulting in 114 fatalities. While fatal rollover crashes were only one-third of all fatal crashes involving these bus types, they represent more than half of all the occupant fatalities. Further, approximately two-thirds of the rollover crash fatalities were attributable to occupant ejections.

In developing today’s NPRM, the agency turned to United Nations Economic Commission for Europe

Regulation 66 (ECE R.66).⁸ Today’s NPRM proposes a test for rollover structural integrity based on the complete vehicle rollover test of ECE R.66. We also examined the school bus roof crush standard set forth in Federal Motor Vehicle Safety Standard (FMVSS) No. 220, “School bus rollover protection,” but chose to base our new standard on ECE R.66’s complete vehicle test because the latter appears to more closely simulate a real-world rollover crash involving the large bus types that are associated with the highest crash risk. Further, an ECE R.66-based test enables us to better evaluate particular aspects of performance that are pertinent for safety of these types of buses (e.g., the affixing of side glazing panels—an area of concern of MAP-21—and attachment of overhead luggage racks). Using a procedure based on ECE R.66 also furthers NHTSA’s efforts to harmonize with international standards when feasible.

This NPRM proposes performance requirements that the buses must meet when tested by NHTSA using an ECE R.66-based test. The vehicle is placed on a tilting platform that is 800 mm above a smooth and level concrete surface. One side of the tilting platform along the length of the vehicle is raised at a steady rate of not more than 5 degrees/second until the vehicle becomes unstable, rolls off the platform, and impacts the concrete surface below.

The rollover structural integrity test is illustrated below in Figure 1.

⁵ Moving Ahead for Progress in the 21st Century Act, Pub. L. 112–141.

⁶ See MAP-21, §§ 32703(b)z6–(b)(1).

⁷ *Id.*, §§ 32703(b)(2).

⁸ Uniform Technical Prescriptions Concerning the Approval of Large Passenger Vehicles with Regard to the Strength of their Superstructure, ECE R.66, February 2006, <http://live.unece.org/fileadmin/DAM/trans/main/wp29/wp29regs/r066r1e.pdf>.

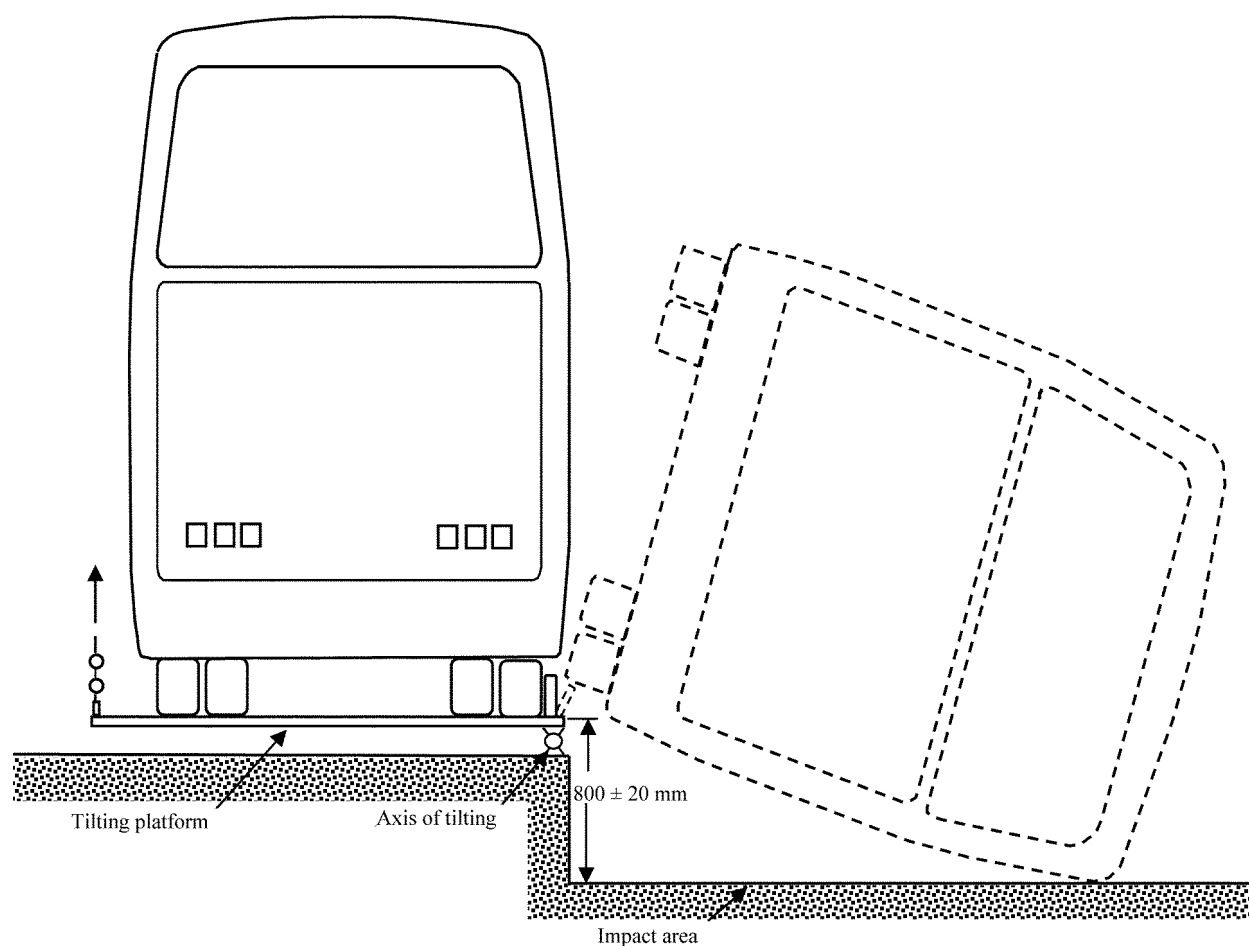


Figure 1: Vehicle on Tilting Platform

The following are the main proposed performance requirements that buses covered by this proposed rule must meet when subjected to the rollover structural integrity test:

(1) Intrusion into the "survival space," demarcated in the vehicle interior, by any part of the vehicle outside the survival space is prohibited;

(2) each anchorage of the seats and overhead luggage racks must not completely separate from its mounting structure;

(3) emergency exits must remain shut during the test and must be operable in the manner required under FMVSS No. 217 after the test; and

(4) each side window glazing opposite the impacted side of the vehicle must remain attached to its mounting such that there is no opening that will allow the passage of a 102 mm diameter sphere.

We believe these proposed requirements would provide reasonable and needed improvements to the types of buses with the greatest safety risk in rollovers. They supplement the agency's final rule on passenger seat belts. With

passengers more likely to be retained in the bus interior as a result of the agency's seat belt final rule, today's NPRM improves the protective attributes of the occupant compartment in which they are retained.

The proposed requirements for maintaining the survival space and ensuring that seats, overhead luggage racks, and window glazing remain attached to their mounting structures would set a minimum level of structural integrity for these buses, to help prevent dangerous structural intrusions into the occupant survival space. The proposed requirement that emergency exits remain closed during the rollover structural integrity test and operable after the test is to increase the likelihood that emergency exits do not become ejection portals during rollover crashes. The requirement also helps ensure that the emergency exits remain an effective means of egress after the crash.

NHTSA believes that this rulemaking would be cost beneficial.⁹

⁹ NHTSA has developed a Preliminary Regulatory Evaluation (PRE) that discusses issues relating to

The agency estimates the annual cost of this proposed rule to be between \$5.28 million and \$13.26 million (see Table 1 below). The countermeasures may include stronger roof structure, support pillars, and side walls, shock resistant latches for emergency exits, stronger seat and overhead luggage rack anchorages, and improved window mounting, resulting in material costs for each bus covered under today's proposed rule ranging from \$282 to \$507. We estimate the total weight increase will range from 564 to 1,114 pounds (lb) for each of these buses and cost an additional \$2,118 to \$5,523 in fuel per vehicle over the lifetime of the vehicle.

Beyond the benefits attributable to the agency's final rule on seat belts and a potential final rule on electronic stability control (ESC) that also may

the potential costs, benefits and other impacts of this regulatory action. The PRE is available in the docket for this NPRM and may be obtained by downloading it or by contacting Docket Management at the address or telephone number provided at the beginning of this document.

apply to this universe of vehicles,¹⁰ we estimate that requiring new buses of the aforementioned types to meet the proposed performance criteria would save approximately 2 lives annually. In addition, we expect that the proposed rule would reduce the number of seriously injured occupants by approximately 4 annually. Thus, we estimate that approximately 3.1 equivalent lives are saved annually if 15 percent of occupants use seat belts, and

approximately 2.3 equivalent lives are saved annually (undiscounted) if 84 percent of occupants use seat belts (see Table 2 below).

The cost per equivalent life saved is estimated to be \$2.09 million to \$4.72 million when belt use is estimated to be 15 percent, and \$2.91 million to \$6.42 million when belt use is estimated to be 84 percent (see Table 3 below). The net cost/benefit impact ranges from a net benefit of \$9.47 million to \$19.35

million if seat belt usage is 15 percent. If the seat belt usage rate is 84 percent, the estimated net cost/benefit impact ranges from a net benefit of \$4.69 million to a net benefit of \$13.06 million (see Table 4 below). While the cost and benefits of this rule will vary depending on the material/fuel costs per vehicle and on the belt use rate, all the available information indicate that this proposed rule—if made final—would be cost beneficial.

TABLE 1—ESTIMATED ANNUAL COSTS
[2010 Dollars]

Potential Costs:	
Material Costs Per Vehicle	\$282 to \$507.
Material Costs, Total New Fleet	\$0.6 million to \$1.1 million.
Fuel Costs per Vehicle @3%	\$2,814 to \$5,523.
Fuel Costs per Vehicle @7%	\$2,118 to \$4,156.
Fuel Costs, Total New Fleet	\$4.7 million to \$12.2 million.
Total Annual Cost	\$5.3 million to \$13.3 million.

TABLE 2—ESTIMATED ANNUAL BENEFITS
[Undiscounted equivalent lives saved]

15 percent belt usage	3.1
84 percent belt usage	2.3

TABLE 3—COST PER EQUIVALENT LIFE SAVED
[Across 3% and 7% discount, 2010 dollars]

15 percent belt usage	\$2.09 million to \$4.72 million.
84 percent belt usage	\$2.91 million to \$6.42 million

TABLE 4—ANNUALIZED COSTS AND BENEFITS
[In millions (M) of 2010 dollars]

	Annual costs	Annual benefits	Net benefits
15% belt usage:			
3% Discount Rate	\$6.81 M—\$13.26 M	\$26.16 M	\$12.9 M—\$19.35 M.
7% Discount Rate	\$5.28 M—\$10.26 M	\$19.73 M	\$9.47 M—\$14.45 M.
84% belt usage:			
3% Discount Rate	\$6.81 M—\$13.26 M	\$19.87 M	\$6.61 M—\$13.06 M.
7% Discount Rate	\$5.28 M—\$10.26 M	\$14.95 M	\$4.69 M—\$9.67 M.

NHTSA has considered retrofit requirements. Based on our tests of older buses, the agency believes that major structural changes to the vehicle's entire sidewall and roof structure would be needed for some existing buses (that are of the type covered by this rule) to meet the rollover structural integrity requirements proposed in today's NPRM. Such structural changes are likely to be cost-prohibitive, making retrofitting for rollover structural integrity quite impractical. Thus, the agency has tentatively not included roof

structure retrofitting requirements for existing vehicles in today's proposal.

However, today's NPRM proposes requirements for emergency exit integrity and operability and side window glazing retention through enhanced structural integrity, aspects of performance included in § 32703(b)(2) of MAP-21. Section 32703(e)(2)(A) of MAP-21 states that "the Secretary may assess the feasibility, benefits, and costs with respect to the application of any requirement established under [§ 32703(b)(2)] to motorcoaches

manufactured before the date on which the requirement applies to new motorcoaches." Subsection (e) states that the Secretary shall submit a report on the assessment to Congress not later than July 2014. Thus, the agency is requesting comments on the feasibility, benefits, and costs of any potential requirement to retrofit existing buses with stronger emergency exit mechanisms and enhanced structural integrity to increase side window glazing retention to afford a similar level

¹⁰ An ESC rulemaking for the buses is also included in MAP-21. The statute directs us to

consider requiring motorcoaches to be equipped with stability enhancing technology, such as ESC,

to reduce the number and frequency of rollover crashes. See § 32703(b)(3).

of anti-ejection protection for passengers riding in existing buses.

II. Background

Each year, the motorcoach industry transports millions of people for long and short distance travel, tours, school field trips, commuter, and entertainment-related trips. According to the 2008 Motorcoach Census,¹¹ there were 3,432 over-the-road bus carriers in the United States and Canada in 2007. These carriers operated over 33,536 over-the-road buses,¹² logged 751 million trips made by passengers, and traveled over 1.8 billion miles yearly. The services provided by over-the-road buses in 2007 included charter services (46.4 percent of the miles driven), moving people between cities or between cities and rural areas (26.5 percent of the miles driven), transporting people between home and work (10.3 percent of the miles driven), and shuttle services to and from the airport (3.4 percent of the miles driven). In 2007, each over-the-road bus was driven an average of 54,000 miles.

Over the ten year period between 2000 and 2009, there were 45 fatal crashes of cross-country/intercity buses resulting in 134 occupant fatalities¹³ according to the FARS data¹⁴ collected by the agency. During this period, on average, 13 fatalities (11 passengers and 2 drivers) have occurred annually to occupants of cross-country/intercity buses. This field and market data suggest that over-the-road (cross-

country/intercity) bus transportation overall is a relatively safe form of transportation.

However, given the high occupancy of over-the-road buses (and the other large buses considered in today's proposed rule) and the speed at which they travel, a single crash can result in a significant number of fatal or serious injuries. Therefore, in this NPRM, the agency is proposing to enhance the safety of these vehicles by improving their crashworthiness relative to crush resistance, structural integrity, and reducing portal openings during rollover crashes.

a. NHTSA's Statutory Authority

NHTSA is proposing today's NPRM pursuant to its authority under the Motor Vehicle Safety Act and the relevant provisions of MAP-21.

National Traffic and Motor Vehicle Safety Act

Under 49 U.S.C. Chapter 301, Motor Vehicle Safety (49 U.S.C. 30101 et seq.), the Secretary of Transportation is responsible for prescribing motor vehicle safety standards that are practicable, meet the need for motor vehicle safety, and are stated in objective terms. "Motor vehicle safety" is defined in the Motor Vehicle Safety Act as "the performance of a motor vehicle or motor vehicle equipment in a way that protects the public against unreasonable risk of accidents occurring because of the design, construction, or performance of a motor vehicle, and against unreasonable risk of death or injury in an accident, and includes nonoperational safety of a motor vehicle." "Motor vehicle safety standard" means a minimum performance standard for motor vehicles or motor vehicle equipment. When prescribing such standards, the Secretary must consider all relevant, available motor vehicle safety information. The Secretary must also consider whether a proposed standard is reasonable, practicable, and appropriate for the types of motor vehicles or motor vehicle equipment for which it is prescribed and the extent to which the standard will further the statutory purpose of reducing traffic accidents and associated deaths. The responsibility for promulgation of Federal motor vehicle safety standards is delegated to NHTSA.¹⁵ ¹⁶ In making

the proposals in today's NPRM, the agency carefully considered all the aforementioned statutory requirements.

Motorcoach Enhanced Safety Act of 2012 (Incorporated in MAP-21)

On July 6, 2012, President Obama signed MAP-21, which incorporated the "Motorcoach Enhanced Safety Act of 2012" into Subtitle G.¹⁷ Section 32703(b) of MAP-21 requires the Secretary to prescribe standards that would address certain aspects of motorcoach crash performance within two years if the Secretary determines that the standards would meet the requirements and considerations of §§ 30111(a) and (b) of the Motor Vehicle Safety Act.¹⁸ There are two subsections of § 32703(b) that are particularly relevant to this NPRM. Subsection (b)(1) specifies that the Secretary is to establish improved roof and roof support standards that "substantially improve the resistance of motorcoach roofs to deformation and intrusion to prevent serious occupant injury in rollover crashes involving motorcoaches." Subsection (b)(2) directs the Secretary to "consider advanced glazing standards for each motorcoach portal and [to] consider other portal improvements to prevent partial and complete ejection of motorcoach passengers, including children."¹⁹

MAP-21 contains various other provisions that are relevant to this rulemaking. Section 32702 states that "motorcoach" has the meaning given to the term "over-the-road bus" in section 3038(a)(3) of the Transportation Equity Act for the 21st Century (TEA-21).²⁰ Section 3038(a)(3) of TEA-21 (*see* 49 U.S.C. 5310 note) defines "over-the-road bus" as "a bus characterized by an elevated passenger deck located over a baggage compartment." However, § 32702 of MAP-21 excludes transit buses and school buses from the "motorcoach" definition.²¹

safety standards for commercial motor vehicles and equipment subsequent to initial manufacture when the standards are based upon and similar to a Federal Motor Vehicle Safety Standard promulgated, either simultaneously or previously, under chapter 301 of title 49, U.S.C.

¹⁷ *See* Moving Ahead for Progress in the 21st Century Act, Pub. L. 112-141 (Jul. 6, 2012).

¹⁸ *See id.* at § 32703(b).

¹⁹ While today's NPRM is mainly aimed at addressing the rollover structural integrity of specific large bus types, the proposed rule also addresses some of the safety risks associated with occupant ejection through side window glazing retention and emergency exit requirements. Thus, both subsection (b)(1) and subsection (b)(2) are relevant to this notice.

²⁰ *See* Moving Ahead for Progress in the 21st Century Act, Pub. L. 112-141, § 32702(6).

²¹ *See id.* at § 32702(6)(A)-(B).

¹¹ The "2008 Motorcoach Census," funded by the American Bus Association (ABA), defines a motorcoach as an over-the-road bus, designed for long-distance transportation of passengers, characterized by integral construction, and with an elevated passenger deck located over a baggage compartment. *See* "Motorcoach Census 2008, A Benchmarking Study of the Size and Activity of the Motorcoach Industry in the United States and Canada in 2007." Paul Bourquin, Economist and Industry Analyst, December 18, 2008. The buses included in the 2008 Motorcoach Census are over-the-road buses that are at least 35 feet in length and have a capacity of more than 30 passengers. Traditionally, these over-the-road buses are considered to be motorcoaches. We note that this rule would apply to a larger set of vehicles than those within the ABA's definition of motorcoach, and therefore the statistics from the 2008 Motorcoach Census presented in this section are only applicable to over-the-road buses.

¹² The 2008 Motorcoach Census defines motorcoaches to include a smaller set of vehicles than those covered by this NPRM. Thus, we have used the term "over-the-road buses" to describe the set of vehicles referenced by the 2008 Motorcoach Census.

¹³ There was one cross-country/intercity bus fire in 2005 in Wilmer, Texas where 23 bus occupants died. The 134 occupant fatalities in cross-country/intercity buses does not include the 23 fatalities from the bus fire since it did not occur as a result of a bus crash or rollover.

¹⁴ The FARS database categorizes the vehicle body type of over-the-road buses as cross-country/intercity buses.

¹⁵ *See* 49 CFR 1.95.

¹⁶ The Secretary also delegated to NHTSA the authority set out for Section 101(f) of Public Law 106-159 to carry out, in coordination with the Federal Motor Carrier Safety Administrator, the authority vested in the Secretary by subchapter 311 and section 31502 of title 49, U.S.C., to promulgate

MAP-21 further directs the Secretary to apply any regulation prescribed in accordance with § 32703(b) (and several other subsections) to all motorcoaches manufactured more than 3 years after the date on which the regulation is published.²² In addition, the Secretary may assess the feasibility, benefits, and costs of applying any requirement established under § 32703 (b)(2) to “motorcoaches manufactured before the date on which the requirement applies to new motorcoaches” (retrofit).²³ Finally, MAP-21 also authorizes the Secretary to combine the required rulemaking actions as the Secretary deems appropriate.²⁴

b. NHTSA’s 2007 Approach to Motorcoach Safety

In 2007, NHTSA undertook a comprehensive review of motorcoach safety issues and the course of action that the agency could pursue to address them. The agency considered various prevention, mitigation, and evacuation approaches in developing the course of action. Many considerations were factored into determining the priorities, including: cost and duration of testing, development, and analysis required; likelihood that the effort would lead to the desired and successful conclusion; target population and possible benefits that might be realized; and anticipated cost of implementing the ensuing requirements into the motorcoach fleet.

The result was NHTSA’s 2007 plan, *NHTSA’s Approach to Motorcoach Safety* (Docket No. NHTSA–2007–28793–001), in which we identified the following areas as the highest priorities for possible near term regulatory action to enhance motorcoach safety: (1) Passenger ejection; (2) rollover structural integrity; (3) emergency egress; and (4) fire safety.

For passenger ejection (action (1) above), we pursued the incorporation of passenger seat belts as the most effective and expeditious way to mitigate ejection. The agency’s seat belt rulemaking, discussed further below, began NHTSA’s implementation of our Motorcoach Safety Plan. Today’s document advances the implementation of the plan.

c. DOT’s 2009 Task Force Action Plan

In 2009, DOT issued a Departmental Motorcoach Safety Action Plan, which outlined a Department-wide strategy to

enhance motorcoach safety.²⁵ An update of the plan was issued on December 2012.²⁶ In addition to the four priority action items specified in NHTSA’s 2007 plan, the 2009 DOT plan, and the 2012 updated plan identified additional factors for enhancing motorcoach safety, such as electronic stability control systems (ESC), event data recorders (EDRs), and driver fatigue and operator maintenance issues. Various DOT agencies are working on the motorcoach safety initiatives related to their administrations.

d. NTSB Recommendations

As a part of its motorcoach crash investigations, NTSB has issued recommendations to NHTSA relating to actions that NTSB believes could improve motorcoach safety. The following NTSB recommendations related to motorcoach structural integrity pertain to this NPRM.

In an NTSB Highway Special Investigation Report (1999), *Bus Crashworthiness Issues*,²⁷ NTSB cited an October 1971 rollover of a 1970 Motor Coach Industries (MCI) bus as justification for the following recommendations:

“H–99–50 (MW): In 2 years, issue performance standards for motorcoach roof strength that provide maximum survival space for all seating positions and that take into account current typical motorcoach window dimensions.”

“H–99–51: Once performance standards have been developed for motorcoach roof strength, require newly manufactured motorcoaches to meet those standards.”

In November 2009, after investigating an August 2008 Sherman, Texas bus crash,²⁸ the NTSB issued two new safety recommendations. In this rollover crash, the failure of the overhead luggage rack on the vehicle impeded passenger egress and rescue efforts. Thus, NTSB stated that the Sherman accident and NHTSA’s motorcoach testing indicate that the lack of standards for overhead luggage racks on motorcoaches leaves passengers at risk of serious injury from interaction

with overhead luggage racks in a crash and made the following recommendations:

“H–09–23: Develop performance standards for newly manufactured motorcoaches to require that overhead luggage racks remain anchored during an accident sequence.”

“H–09–24: Develop performance standards for newly manufactured motorcoaches that prevent head and neck injuries from overhead luggage racks.”

In June 2010, after investigating a 2009 motorcoach rollover crash in Dolan Springs, the NTSB issued two additional recommendations:

“H–10–03: In your rulemaking to improve motorcoach roof strength, occupant protection, and window glazing standards, include all buses with a gross vehicle weight rating above 10,000 pounds, other than school buses.”

“H–10–04: Develop performance standards for all newly manufactured buses with a gross vehicle weight rating above 10,000 pounds to require that overhead luggage racks are constructed and installed to prevent head and neck injuries and remain anchored during an accident sequence.”

e. NHTSA’s Seat Belt Final Rule

Completing the first initiative of NHTSA’s 2007 “NHTSA’s Approach to Motorcoach Safety” plan and one of the principal undertakings of DOT’s 2009 Motorcoach Safety Action Plan, and fulfilling a statutory mandate of the Motorcoach Enhanced Safety Act, NHTSA issued a final rule amending FMVSS No. 208, “Occupant crash protection.” The final rule required lap/shoulder seat belts for each passenger seating position in: (a) All new over-the-road buses; and (b) in new buses other than over-the-road buses, with a GVWR greater than 11,793 kg (26,000 lb).²⁹ (The notice of proposed rulemaking preceding the final rule called buses with GVWR greater than 11,793 kg (26,000 lb) “motorcoaches.”)

NHTSA’s safety research on seat belts in large buses (greater than 11,793 kg (26,000 lb) GVWR) completed in 2009, showed that the installation of lap/shoulder belts on the vehicles is practicable and effective and could reduce the risk of fatal injuries in rollover crashes by 77 percent, primarily by preventing occupant ejection. Lap/shoulder belts are also highly effective in preventing fatalities and serious injuries in frontal crashes, and will

²⁵ http://www.fmcsa.dot.gov/documents/safety-security/MotorcoachSafetyActionPlan_finalreport-508.pdf.

²⁶ <http://www.fmcsa.dot.gov/safety-security/pcs/Motorcoach-Safety-Action-Plan.aspx>.

²⁷ National Transportation Safety Board, 1999, *Bus Crashworthiness Issues*. Highway Special Investigation Report NTSB/SIR–99/04. Washington, DC.

²⁸ NTSB/HAR–09/02 PB2009–916202; Motorcoach Run-Off-the-Bridge and Rollover Sherman, Texas August 8, 2008; October 2009; <http://www.nts.gov/doclib/reports/2009/HAR0902.pdf>.

²² See *id.* at § 32703(e)(1).

²³ See *id.* at § 32703(e)(2). “Retrofit Assessment for Existing Motorcoaches.”

²⁴ See *id.* at § 32706.

²⁹ Some buses are excluded from this latter category, such as transit buses, school buses, and buses with perimeter-seating.

enhance protection in side crashes in the affected buses. By requiring passenger lap/shoulder seat belts on (a) new over-the-road buses, and (b) new buses, other than over the road buses, with a GVWR greater than 11,793 kg (26,000 lb), the final rule significantly reduces the risk of fatality and serious injury in frontal crashes and the risk of occupant ejection in rollovers, thus considerably enhancing the safety of these vehicles.

III. Safety Need

The rulemakings that are being conducted pursuant to the requirements of the Motor Vehicle Safety Act and MAP-21, and as part of NHTSA's Approach to Motorcoach Safety and the DOT Motorcoach Safety Action Plan, explore whether there are unreasonable safety risks associated with motorcoach transportation. If there are such risks, we explore whether those safety risks can be reasonably reduced by having minimum levels of performance specified for crashworthiness and crash avoidance standards, such as a standard for rollover structural integrity.

NHTSA found in the seat belt final rule that, generally, a significant majority of fatalities are attributable to rollovers. Because more than three-quarters of rollover fatalities are attributable to ejections, NHTSA issued a seat belt requirement to mitigate those ejections. For purposes of today's proposal, we believe that, hand-in-hand with that seat belt proposal, there is a need to ensure enhanced structural integrity of the interior of these buses, to better protect the restrained occupants who, due to the belts, will be retained in the bus interior. Moreover, independent of a seat belt requirement, we believe that more can be done to improve the vehicle structure to reduce the likelihood of ejection of occupants who may not be restrained at the time of the crash. For instance, emergency exits should not open during a rollover crash (an open emergency exit forms a portal through which occupants could

be ejected). Today's NPRM proposes requirements to meet these objectives.

a. FARS Data and Recent Crashes

To determine the types of vehicles that should be covered by the rulemakings conducted pursuant to the Motor Vehicle Safety Act and MAP-21 and as part of the NHTSA's Approach to Motorcoach Safety plan and the DOT Motorcoach Safety Action Plan, the agency examined FARS data files to gain a better understanding of fatal crashes involving over-the-road buses and other bus types.³⁰ FARS contains data on a census of fatal traffic crashes within the 50 States, the District of Columbia, and Puerto Rico. To be included in FARS, a crash must involve a motor vehicle traveling on a traffic way customarily open to the public, and must result in the death of an occupant of a vehicle or a non-occupant within 30 days of the crash.

For the seat belt rulemaking and other "motorcoach" rulemakings, we analyzed 10 years of FARS data to assess what type of vehicle should be covered by NHTSA's motorcoach safety plan initiatives. We analyzed FARS data of high-occupancy vehicles (buses) that are in fatal crashes. FARS data for fatalities of occupants in high occupancy vehicles (buses with a GVWR greater than 4,536 kg (10,000 lb), other than school buses and transit buses) over 10 years show that 83 percent of the occupant fatalities were in buses with a GVWR greater than 11,793 kg (26,000 lb). Based on these data, NHTSA determined that the vehicles of significance are those with a GVWR of greater than 11,793 kg (26,000 lb). These buses appear to have a higher risk of involvement in fatal crashes involving passenger fatalities than buses with a GVWR of 11,793 kg (26,000 lb) or less.

³⁰ Previous discussions of the FARS data is set forth in the seat belt final rule, and in the DOT 2009 Motorcoach Action Plan, <http://www.nhtsa.gov/staticfiles/DOT/NHTSA/reports/HS811177.pdf>.

For the seat belt final rule and for purposes of today's NPRM, the agency analyzed FARS data for vehicles coded in FARS as "cross-country/intercity buses," "other buses," and "unknown buses."³¹ Among these buses (cross-country/intercity buses, other buses, unknown buses) with a GVWR greater than 11,793 kg (26,000 lb), there were a total of 209 occupant fatalities³² in crashes during the 10-year period between 2000–2009. This number includes 134 occupant fatalities in cross-country/intercity buses, 47 in other buses, and 28 in unknown buses (see Figure 1 and Table 5 below). In contrast, with regard to buses with a GVWR less than 11,793 kg (26,000 lb), there were a total of 44 fatalities in cross-country/intercity buses, other buses, and unknown buses with a GVWR of 11,793 kg (26,000 lb) or less in the 2000–2009 FARS data files. This is approximately one-fifth of the fatalities in such buses with a GVWR greater than 11,793 kg (26,000 lb).

³¹ The FARS database has five bus body type categories: (1) Cross-country/intercity bus, (2) transit bus, (3) school bus, (4) other bus, and (5) unknown bus. Transit bus and school bus body types were excluded from the analysis because they are easily recognized and categorized as such by crash investigators and those coding the FARS data. Thus, those vehicles are unlikely to be miscoded as other buses.

³² There were 232 occupant fatalities in the large bus types considered in today's NPRM during this 10-year period. However, 23 fatalities occurred due to a fire (Wilmer, Texas bus fire) and were not related to a crash event and therefore are not included in the fatality count resulting from crashes.

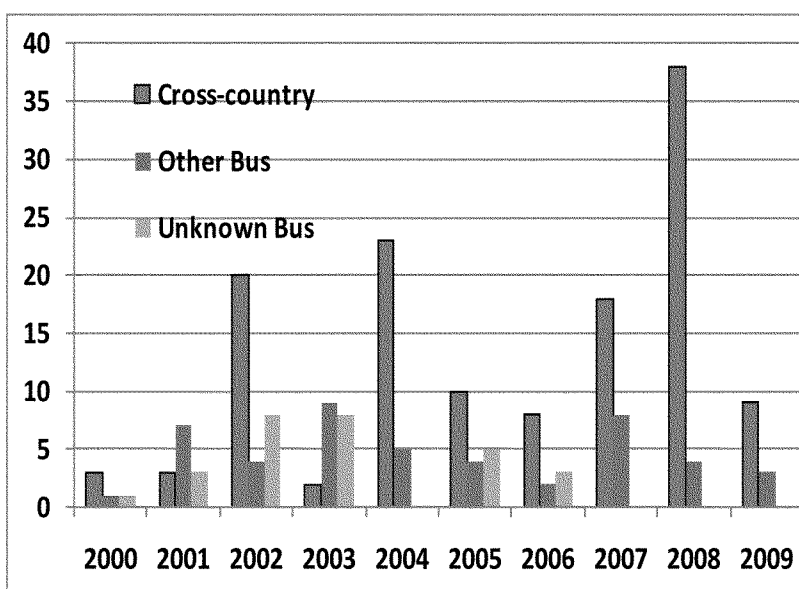


Figure 1: Number of bus occupant fatalities in crashes involving cross-country, other, and unknown buses with a GVWR > 11,793 kg (26,000 lb) except for transit and school buses (categorized by bus body type). (FARS 2000-2009 data files.)

TABLE 5—NUMBER OF BUS OCCUPANT FATALITIES IN CRASHES BY BUS BODY TYPE, GVWR, AND OCCUPANT TYPE. FARS 2000–2009 DATA FILES

GVWR (lb)	Bus body type							
	Cross-Country		Other		Unknown		Total	
	Driver	Pass	Driver	Pass	Driver	Pass	Driver	Pass
10,000–26,000	0	2	5	26	2	7	7	35
>26,000	22	112	11	36	8	20	41	168

Among the 209 occupant fatalities in the 10-year period, the FARS data show that 168 (80 percent) were passengers, and 41 (20 percent) were drivers. In addition, the data show that 64 percent of the fatalities were in cross-country/intercity buses and 36 percent were in the other bus and unknown bus categories (see Table 5 above).

As shown in Figure 1, fatalities in certain years are significantly higher than average. There were more than 20 occupant fatalities in 2002, 2004, 2007, and 2008 in crashes involving these vehicles. We note that such increases in fatality statistics were often attributable to a small number of serious crashes during that year which caused a large number of fatalities.

For example, the majority of fatalities in 2004 resulted from a crash in Arkansas, which involved a bus hitting a highway signpost and subsequently rolling over. The rollover and partial detachment of the roof resulted in the ejection of all 30 occupants. This crash

resulted in 15 fatalities, including the driver. All 14 passengers who died in this crash were ejected.

The 42 passenger fatalities in 2008 were mainly a result of 3 separate crashes. The first event was a rollover crash that occurred in Mexican Hat, Utah, where the bus overturned as it departed the roadway and rolled one full turn, striking several rocks in a drainage ditch bed at the bottom of the embankment, and came to rest on its wheels. The roof of the vehicle separated from the body, and 51 of the 53 occupants were ejected. Nine passengers were fatally injured and 43 passengers and the driver received various injuries.

The second 2008 event was a crash in Sherman, Texas, where the bus went through the bridge railing and off the bridge. As a result of the accident, 17 passengers died. Among the NTSB findings, the report concluded that the overhead luggage rack had detached from its mounting and fell diagonally

across the aisle onto the passengers and impeded passenger egress and rescue efforts.

The third 2008 event was a rollover crash near Williams, California, where the bus flipped and rolled into a ditch, killing 9 people and injuring more than 30 others. According to a media report,³³ 30 to 38 people suffered critical injuries, while the rest of the passengers received moderate to minor injuries. Approximately a dozen passengers were ejected from the vehicle.

Separately, in 2009, a large number of fatalities were a result of a January 30, 2009 crash in which a 29-passenger tour bus overturned on a highway near the Hoover Dam, killing 7 occupants and injuring 10 others. According to the

³³ <http://www.kcra.com/news/17630435/detail.html>.

NTSB report,³⁴ the 29-passenger mid-size bus veered left out of its lane. After the driver overcorrected, the bus rolled 1.25 times before stopping. During the rollover, 15 of the 17 occupants were fully or partially ejected.

b. Rollover and Ejection Statistics

Using the aforementioned FARS bus type categories, the agency examined

the FARS data to understand the proportion of occupant fatalities that resulted from rollover crashes and occupant ejections. The FARS data show that rollovers account for more than half of the occupant fatalities in these bus types. Figure 2, below, shows the 209 fatalities categorized by rollover/first impact point for the 10-

year period 2000–2009. If a vehicle was involved in a rollover, it is categorized as a rollover crash since it is generally the most harmful event in a crash and results in most of these fatalities. Vehicles not involved in a rollover are categorized by first impact point (front, side, and rear).

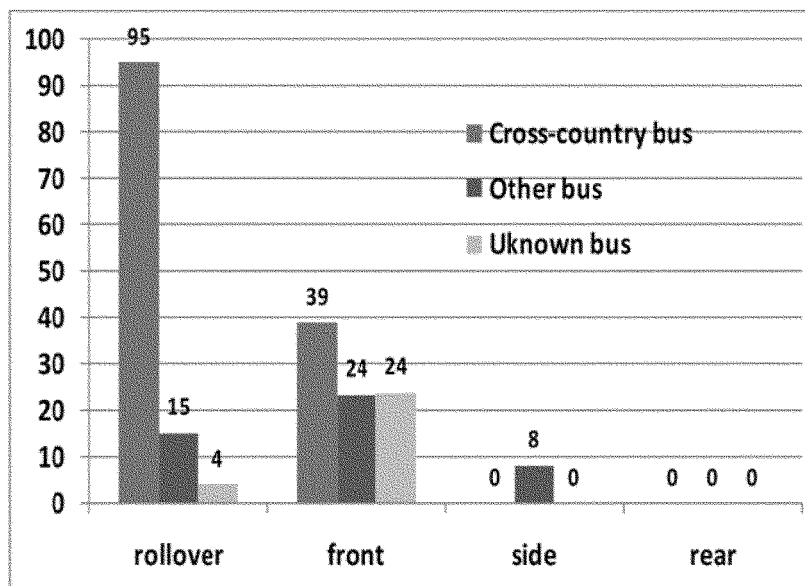


Figure 2. Number of occupant fatalities involving cross-country, other, and unknown buses with a GVWR > 11,793 kg (26,000 lb) except for transit and school buses, by rollover/first impact point and bus body type.

Among the 209 occupant fatalities, rollovers accounted for 114 fatalities (55 percent). Also, 71 percent of crash fatalities in cross-country buses were in rollover crashes, while 25 percent of the fatalities in other and unknown buses were in rollover crashes. There were no fatalities in rear and side impacts in cross-country and unknown bus body type categories.

The agency further examined these data and found that the vast majority of fatalities in rollover crashes involve occupant ejections. Figure 3 shows the distribution of fatalities in rollover crashes involving these bus types (cross-country, other, and unknown buses with a GVWR greater than 11,793 kg (26,000 lb)) by occupant type and ejection status. For the ten year period from 2000

to 2009, there were 32 fatal rollover crashes, resulting in 114 fatalities. In these rollover crashes, two thirds (78 out of 114) of the fatalities were occupants who were ejected. Three drivers (3 percent) involved in rollover crashes were ejected.

³⁴ NTSB/HAR-10/01 PB2010-916201; Bus Loss of Control and Rollover Dolan Springs, Arizona; January 30, 2009.

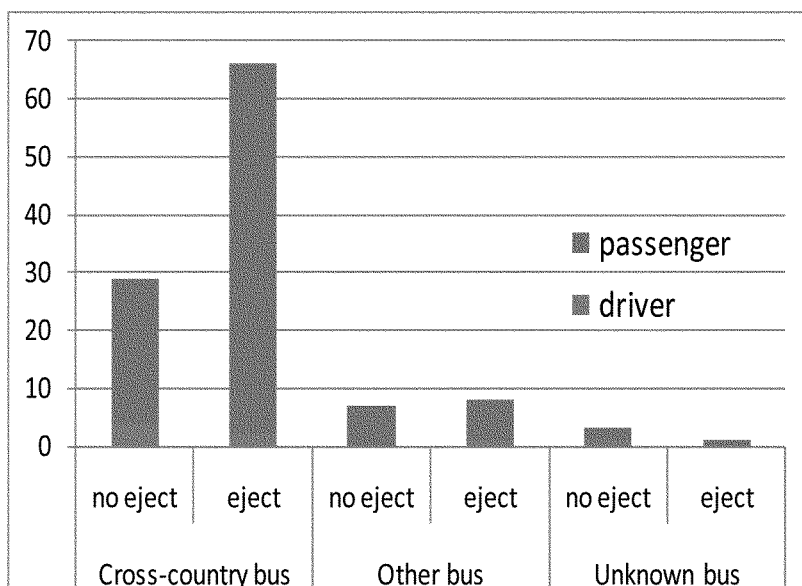


Figure 3. Number of rollover fatalities in cross-country, other, and unknown buses with a GVWR > 11,793 kg (26,000 lb) except for transit and school buses, among drivers and passengers by ejection status and bus body type.

While a large percentage of fatalities in rollover crashes are due to the occupants being ejected, some fatalities can be attributed to the collapse of structure during the rollover event. On May 31, 2011, a 2000 Setra bus carrying 58 passengers from Greensboro, North Carolina to New York City on Interstate 95 departed the roadway near Doswell, Virginia, rolled 180 degrees, and landed on its roof. NTSB, which is investigating this accident, noted that there was considerable deformation of the roof into the occupant survival space as evidenced by the seat back deformation resulting from contact with the roof structure. The passenger seats were not equipped with seat belts. Four passengers were killed as a result of encroachment of the occupant survival space by the roof and fourteen passengers sustained serious injuries. The driver, restrained by a lap belt, was not injured.

The agency is proposing the requirements in today's NPRM to improve rollover safety in large buses. The aforementioned data show that crashes involving rollovers and ejections present the greatest risk of death to the occupants of these buses. The majority of fatalities occur in rollovers, and two-thirds of rollover fatalities are associated with occupant ejection, particularly passenger ejection. There is also real world evidence that bus occupants retained in the bus during rollover events may sustain serious to fatal injuries due to structural

collapse. The proposed requirements work in conjunction with the seat belt requirements by enhancing the protection of restrained and retained occupants in rollovers and reducing the risk of ejection of occupants who are not restrained.

IV. NHTSA's Large Bus Rollover Structural Integrity Research

In support of this rulemaking initiative, the agency evaluated two existing roof crush/rollover standards: FMVSS No. 220, "School bus rollover protection," and ECE R.66, "Uniform Technical Prescriptions Concerning the Approval of Large Passenger Vehicles with Regard to the Strength of their Superstructure."³⁵ We sought to evaluate the extent to which the standards would address the aforementioned safety concerns, particularly as to providing a minimum level of protection for vehicle occupants who are retained in the vehicle after a rollover.

The agency purchased three different bus models for this test program. Two

older models were selected because they were representative of the range of roof characteristics (such as design, material, pillars, shape, etc.) of large bus roofs in the U.S. fleet. The vehicles selected were two 12.2 meters (m) (40 feet) long MY 1992 MCI model MC-12, and two 12.2 m (40 feet) long MY 1991 Prevost model (Prevost) LeMirage buses. The MCI and Prevost models were selected because they were similar in size and weight but exhibited visible differences in construction. The most discernible difference between these two models was that of the two, the Prevost LeMirage had smaller side windows and more roof support pillars.

Many buses, newer than those MCI and Prevost models, are 13.7 m (45 feet) instead of 12.2 m (40 feet) in length. Thus, the agency believed that manufacturers could have significantly redesigned their bus models when introducing the longer designs. Thus, the agency also procured a MY 2000 MCI bus, Model 102-EL3, that was 13.7 m (45 feet) in length.

All five of the buses purchased were tested to requirements in either FMVSS No. 220 or ECE R.66. For further information on the four older buses tested, a detailed discussion of the tests and results are available in the docket entry NHTSA-2007-28793-0019. For further information on the newer vehicle tested, see the test report, "ECE Regulation 66 Based Research Test of Motorcoach Roof Strength, 2000 MCI 102-EL3 Series Motorcoach, NHTSA

³⁵ ECE R.66 defines "superstructure" as "the load-bearing components of the bodywork as defined by the manufacturer, containing those coherent parts and elements which contribute to the strength and energy absorbing capability of the bodywork, and preserve the residual space in the rollover test." "Bodywork" means "the complete structure of the vehicle in running order, including all the structural elements which form the passenger compartment, driver's compartment, baggage compartment and spaces for the mechanical units and components." (Footnote added.)

No.: MY0800,” October 1, 2009, Report No.: ECE 66–MGA–2009–001, which can be found on NHTSA’s Web site.³⁶

a. Findings of the FMVSS No. 220-Based Tests

In evaluating FMVSS No. 220, the agency used one of the MY 1992 MCI buses and one of the MY 1991 Prevost buses.

The FMVSS No. 220 test applies a uniformly distributed compressive load (equivalent to 1.5 times the unloaded vehicle weight (UVW) of the bus), on the roof of the bus along the vehicle’s longitudinal centerline using a 915 mm (3 feet) wide platen that is 305 mm (1 foot) shorter than the bus length. The requirements are that the bus roof must not compress more than 130 mm (5.118 inches) and that the emergency exits remain operable.

Since there were some uncertainties regarding the strength of the bus roofs and whether they could withstand a force of 1.5 times the unloaded vehicle weight (UVW), we slightly changed how the FMVSS No. 220 test was conducted. In particular, when the applied force reached the magnitude of 0.5 times UVW and 1.0 times UVW, the force was held constant at that level for a period of time in order to examine the operability of the emergency exits. In addition, survival space templates³⁷ (similar to those used in the ECE R.66 test) were installed for comparison with the results with the ECE R.66 tests.

Neither the MY 1992 MCI nor the MY 1991 Prevost bus was able to meet the 1.5 times the UVW required for school buses. For the MCI bus, a peak load of 0.91 times UVW was achieved when the force application device reached its maximum displacement range. Approximately 13 seconds after the peak force was recorded, contact was made between the front survival space template and the left and right overhead luggage racks. The emergency exit windows were operable after the load reached 0.5 times UVW and after the test with the load removed.

For the MY 1991 Prevost bus, a peak load of 1.17 times UVW was achieved during the test. This peak load was

reached when the force application device reached its maximum displacement range. Approximately 12 seconds after the peak load was reached, contact was made between the front survival space template and the left and right overhead luggage racks. The emergency exit windows were operable after the load reached 0.5 times UVW and after the test with the load removed. However, no measurements were made at 1.0 times UVW for safety reasons.

We made the following observations from the tests. Even though the buses we tested were heavier, larger, and structurally different than school buses,³⁸ the testing demonstrated that FMVSS No. 220’s test protocol could be adapted to test these vehicles with only minor changes to the test device and procedure for mounting and stabilizing the bus on the test device. The testing further showed that the front sections of these two bus models are weaker than the back. We believe this is because the windshield and service door are located in the front of the bus and offered little resistance to the compressive load. The front of the MY 1992 MCI bus yielded to the compressive load at 0.91 times UVW, while the front of the MY 1991 Prevost bus yielded at 1.17 times UVW.

b. Findings of the ECE R.66-Based Tests

Testing of Older Bus Models

The agency also used one of the MY 1992 MCI buses and one of the MY 1991 Prevost buses to evaluate the ECE R.66 test procedure.

In the ECE R.66 full vehicle test, the vehicle is placed on a tilting platform that is 800 mm above a smooth and level concrete surface. One side of the tilting platform along the length of the vehicle is raised at a steady rate of not more than 5 degrees/second until the vehicle becomes unstable, rolls off the platform, and impacts the concrete surface below. The vehicle typically strikes the hard surface near the intersection between the sidewall and the roof. The encroachment of the survival space during and after the rollover structural integrity test may be assessed using high speed photography, video, deformable templates, electric contact sensors, or any other suitable means.

³⁸ Generally, large bus designs are integral constructions whereas school buses are the traditional body-on-chassis designs. The loads specified in FMVSS No. 220 are applied to the frame structure of the school bus chassis which is easy to identify. In contrast, identifying load bearing points on a large bus can be challenging and requires some understanding of its construction. The location of load bearing points can vary for different designs. In the two large buses tested, the loads were applied at load bearing points near the wheel supports.

In our research, high speed video cameras and transfer media were applied to each survival space template in order to determine if any portion of the vehicle interior had entered the occupant survival space during the rollover crash. In addition, two Hybrid III (HIII) 50th percentile adult male Anthropomorphic Test Devices (ATDs) (test dummies) were installed in the vehicle to measure injury potential and seat anchorage performance.

We observed the following in our tests of the older buses:

- The testing demonstrated that it is practicable to apply the ECE R.66 complete vehicle test to the large buses being considered in today’s NPRM. However, neither of the two buses tested was able to meet the requirement to maintain the integrity of the survival space during and after the test. Contact between the front survival space template and left side window was made on both bus models. As in the FMVSS No. 220-based tests, the testing indicated that the front sections of these two models were weaker than the rear. We believe this is because the windshield and service door are in the front of the bus and offered little resistance upon impact with the ground.
- On both buses, the windows on the impact side remained intact. The high speed video footage from both tests indicated that the side windows located on the far-side of the impact underwent a substantial amount of flexion during the impact with the ground but remained intact. The windshield broke from its mounting and fell to the ground.
- For both buses, the roof emergency exits opened when the bus impacted the ground. The video footage also indicated that the side emergency exit windows on the Prevost bus unlatched and opened but closed when the bus came to its final resting position.
- On the MY 1992 MCI bus, all of the left side overhead luggage rack inboard hangers (hangers connect the overhead luggage rack to the ceiling of the vehicle, and are spaced along the length of the rack to hold it up) rearward of the front two hangers, broke during the impact, leaving exposed sharp metal edges.
- For the MY 1991 Prevost bus, all the seats on the right side (opposite the impact side) of the bus detached from their wall mounts and the seat with the restrained dummy broke completely from its anchorages.
- The Injury Assessment Reference Values (IARVs) were relatively low for the ATDs restrained by the seat belts

³⁶ http://www-nrd.nhtsa.dot.gov/database/aspx/searchmedia2.aspx?database=v&tstno=6797&mediatype=r&r_tstno=6797, Report 8. Step-by-step instructions on accessing the research report can be found in a memorandum in Docket No. NHTSA–2007–28793–0025.

³⁷ The templates are used to delineate the occupant survival space. The templates are 1,250 mm (50.2 inches) tall and are tapered from the sidewall a distance of 150 mm (5.9 inches) at the bottom and 400 mm (15.8 inches) at the top. Several templates are placed in the bus passenger compartment. Encroachment of any bus structure into the survival space, as delineated by the templates, would be prohibited by ECE R.66.

(even for the seat in the Prevost bus that broke away from its side and floor anchorages). However, for the ATDs that were unrestrained, the type and severity of the injury indicated by the dummy IARVs depended on how they fell from their initial seated position during the rollover sequence. In the case of the MCI bus, the unrestrained ATD received only one IARV (neck injury criterion $N_{ij} = 1.10$) that was over the performance limit used in FMVSS No. 208, "Occupant crash protection." However, in the case of the MY 1991 Prevost bus, the unrestrained ATD fell across the bus head-first onto the side window which was in contact with the ground, resulting in multiple IARVs exceeding the performance limits specified in FMVSS No. 208. The dummy resulted in multiple IARVs that were well above the acceptable limits.

Testing of a Newer Bus Model

NHTSA also conducted the ECE R.66 test on a MY 2000 MCI bus Model 102-EL3 that was 13.7 m (45 foot) in length. This test was conducted to determine

whether the ECE R.66 test protocol could be applied to the larger and heavier buses sold in the United States and to examine different ballasting methods. Survival space templates were installed and the vehicle was placed on a tilting platform that was 800 mm above a smooth and level concrete surface. One side of the tilting platform was raised at a steady rate of not more than 5 degrees/second until the vehicle became unstable, rolled off the platform, and impacted the concrete surface below. See, "ECE Regulation 66 Based Research Test of Motorcoach Roof Strength, 2000 MCI 102-EL3 Series Motorcoach, NHTSA No.: MY0800," October 1, 2009, *supra*.

Occupant ballasts were used in the test, as specified in ECE R.66. ECE R.66 specifies the option of two different methods of securing occupant ballast to the passenger seats. NHTSA tested both types of ballasts to determine the feasibility of each and the differences (if any) that exist between the two. The agency believed that ballasting was important because it increases the weight and raises the center of gravity of the vehicle, making the rollover

structural integrity test more stringent and representative of a rollover crash of a fully loaded bus. In addition, the seat anchorages experience the forces in a rollover when the seat is occupied by an average sized restrained occupant.

NHTSA evaluated the two ballasting methods to assess the feasibility and merits of the ballast methods. Four anthropomorphic ballasts, commercially available "water dummies,"³⁹ were installed in one full row of seats (four seating positions) and were secured with ratchet straps that were configured to simulate Type 2 seat belts. The dimensions of the anthropomorphic ballasts used in this test are shown in Figures 5(a) and 5(b), below. The water dummies were each filled with 68 kg (150 lb) of sand. Steel ballasts, 68 kg (150 lb) per seating position, were installed in a second full row of seats (four seats). In this row, steel plates were placed on top of each seat cushion and were secured with bolts that passed through the cushion and attached to a bar which clamped onto the seat frame. (In the ECE R.66 test, each designated seating position with occupant restraints would be ballasted.)

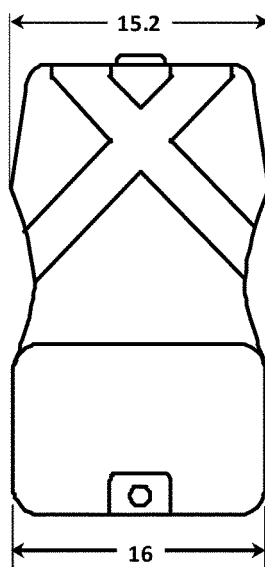


Figure 4(a). Front view of water dummy. All dimensions are in centimeters.

³⁹ These water dummies are plastic containers constructed to simulate the torso shape of a passenger and can be secured in place using belts. Such water dummies have the capacity to be loaded to a weight of 176 pounds (80 kg). However, since

the GVWR of a vehicle is typically estimated using an occupant weight of 150 pounds per seating position and since ECE R.66 specifies ballasts of 150 pounds, the agency only loaded the water dummies to 150 pounds. The water dummies were

filled with sand instead of water because filling the ballast partially with water would cause the water's mass to slosh during the rollover test, possibly introducing some variability.

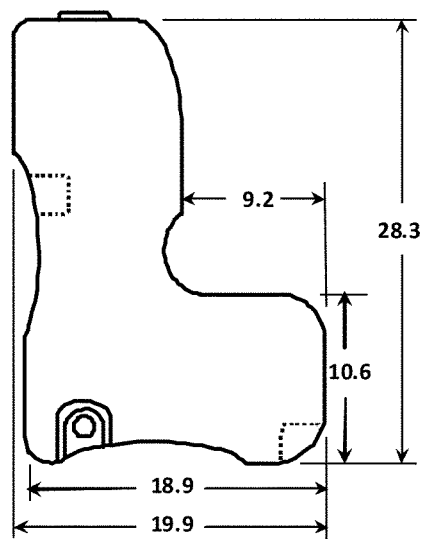


Figure 4(b). Side view of water dummy. All dimensions are in centimeters.

We also seated two 50th percentile adult male ATDs on the opposite side of the impact. This arrangement was similar to the earlier tests with the older buses.

We observed the following in our test of this MY 2000 bus:

- Based on an analysis of image data from the high-speed camera located outside the vehicle, it appears that a side pillar in the front of the vehicle along the impact side may have intruded into the survival space. However, this was not assessed using the survival space templates since they were not located at the position of the side pillar during the test, and there was no contact between the survival space templates and the bus structure.
- During impact, the glazing on five of the seven windows on the right side of the bus (opposite the impacted side) dislodged from their window mounting and fell into the occupant compartment during the test. The glazing in one of the windows was retained by an overhead TV monitor and prevented the window pane from separating from its mounting gasket and falling into the bus. The glazing in the last window near the rear shattered, but was retained and did not fall into the passenger compartment, apparently because the window was shorter in length than the other windows. After the bus impacted the ground, both sides of the windshield lost retention and fell from its supporting structure.
- All side emergency exit windows remained latched during the test. However, both roof emergency exits opened when the roof of the bus impacted the ground.

—The ATD restrained by the seat belt measured forces that were below the FMVSS No. 208 IARVs. However, the unrestrained ATD had multiple IARVs that were well above the acceptable limits.

—In terms of the feasibility of the test procedure, the testing showed that it was possible to ballast the seats with either the anthropomorphic ballast or steel weights. All of the seats with both types of ballast remained attached to their original anchorages.

V. Proposed Requirements

a. Overview

This NPRM proposes performance requirements that the large buses covered by this rulemaking must meet when tested by NHTSA using a test substantially modeled after the complete vehicle test of ECE R.66.⁴⁰ In the rollover structural integrity test, the vehicle would be loaded with up to 68 kg (150 lb) of weight in ballasts at each designated seating position in order to simulate the load of occupants on both vehicle structure and the seat anchorages. The following are the proposed performance requirements when the vehicle is subjected to the rollover structural integrity test:

- (1) Intrusion into the survival space, demarcated in the vehicle interior, by any part of the bus outside the survival space is prohibited;
- (2) each anchorage of the seats and interior overhead luggage racks and

compartments shall not completely separate from its mounting structure;

(3) emergency exits must remain shut during the test and roof and rear emergency exits must be operable in the manner required under FMVSS No. 217 after the test; and

(4) each side window glazing opposite the impacted side of the vehicle must remain attached to its mounting such that there is no opening that will allow the passage of a 102 mm diameter sphere.

b. Applicability

In this rulemaking, the agency's goal is to apply the proposed requirements in today's NPRM to generally the same group of vehicles that are covered by the seat belt final rule. The agency tentatively believes that it would make sense to apply today's proposed requirements generally to the same group of vehicles that are covered by the seat belt final rule. Both rulemakings are intended to address different facets of occupant harm occurring from the rollover event. Both standards would apply to the vehicles associated with unreasonable risk of harm in rollovers. The agency tentatively concludes that this rollover-specific NPRM should apply to high-occupancy vehicles associated with unreasonable risk of fatal rollover involvement and that these vehicles are generally buses with a GVWR greater than 11,793 kg (26,000 lb).

In order to achieve this, the agency proposes to apply the requirements to two types of buses: (a) All new over-the-road buses (regardless of GVWR) and (b) all new buses other than over-the-road buses, with a GVWR greater than 11,793

⁴⁰ECE R.66 includes several "equivalent approval tests," including body section testing and computer simulations. In a later section, we discuss why we believe these alternative compliance methods would not be suitable for incorporation into today's proposed Federal motor vehicle safety standard.

kg (26,000 lb).⁴¹ While the vast majority of over-the-road buses have a GVWR greater than 11,793 kg (26,000 lb), the agency proposes to take this two-prong approach towards determining applicability of the proposed standard in order to cover all of the buses covered by MAP-21 and all of the buses with similar safety risks as the buses covered under MAP-21.

MAP-21 and Over-the-Road Buses

As described above, the large bus rulemaking provisions in MAP-21 apply to “motorcoaches” which are defined as “over-the-road buses.” An over-the-road bus is, in turn, defined as “a bus characterized by an elevated passenger deck located over a baggage compartment.” In order to cover this group of vehicles, we propose in this NPRM to use the language from MAP-21 and apply the proposed requirements to “over-the-road buses.” Further, we propose to adopt the definition incorporated in MAP-21 and define over-the-road buses as buses that are characterized by an elevated passenger deck located over a baggage compartment.⁴²

The agency believes that the vast majority of “over-the-road buses” are buses with a GVWR greater than 11,793 kg (26,000 lb). However, rather than simply applying the proposed requirements to buses (of any type) with a GVWR greater than 11,793 kg (26,000 lb) the agency tentatively believes that it is necessary to propose a separate definition for “over-the-road buses” and apply the proposed requirements to all of those buses. While most over-the-road buses have a GVWR greater than 11,793 kg (26,000 lb), the agency is not aware of any reason why buses characterized by an elevated passenger deck located over a baggage compartment (over-the-road buses) must necessarily have a GVWR greater than 11,793 kg (26,000 lb). As it is possible to design a bus with an elevated passenger deck located over a baggage compartment with a GVWR less than 11,793 kg (26,000 lb), the agency tentatively believes that it is necessary to apply the proposed requirements to all over-the-road buses (regardless of GVWR) in order to cover all the buses contemplated by Congress in MAP-21. In addition, the agency believes that

over-the-road buses (as characterized in MAP-21) are likely to be used for high-speed intercity travel (where rollover crashes are more likely to occur) regardless of the vehicle’s GVWR.

Buses Other Than Over-the-Road Buses With a GVWR Greater Than 11,793 kg (26,000 lb)

However, in addition to the buses contemplated by Congress in MAP-21, the agency proposed to also cover other types of buses⁴³ so long as those buses have a GVWR greater than 11,793 kg (26,000 lb). As discussed in the “Safety Need” section of this preamble, FARS data for 2000–2009 show that rollovers constitute a large safety problem for buses with a GVWR greater than 11,793 kg (26,000 lb). FARS data show that rollovers (32 crashes, 114 fatalities) accounted for 34 percent of the fatal crashes yet more than 50 percent of the occupant fatalities. In these rollover crashes, two-thirds of the fatalities were passengers who were ejected. The data indicate that, for these vehicles, rollover crashes and occupant ejections are more likely to cause fatalities than other types of crashes.

As mentioned earlier, NHTSA is proposing to adopt the requirements in today’s NPRM under its authority in both the Motor Vehicle Safety Act and the relevant provision of MAP-21. While the relevant provisions of MAP-21 instruct this agency to examine “over-the-road buses” (buses characterized by an elevated passenger deck located over a baggage compartment) in any roof strength and anti-ejection rulemakings,⁴⁴ no provision in MAP-21 limits the agency’s ability to examine other types of buses pursuant to its existing authority under the Motor Vehicle Safety Act.

Given the available data, the agency believes that limiting the scope of this rulemaking to “traditional motorcoaches” (over-the-road buses) would be only a partial and incomplete response to the safety problem. As discussed above, the FARS data for 2000–2009 show that buses other than over-the-road buses were often involved in high speed crashes involving multiple passenger fatalities. The FARS data show that 64 percent of the fatalities were in cross-country/intercity buses (considered traditional over-the-road type buses) and 36 percent were in the “other bus” and “unknown bus” categories. While these “other” and

“unknown” buses have a non-traditional (e.g., body-on-chassis) design and appearance, these buses are of a similar size, seating configuration, and function as an over-the-road bus type. As a result, these buses are associated with similar safety risks as over-the-road buses. Thus, the agency is currently unaware of a rationale that would support excluding these “other” and “unknown” buses from today’s proposed requirements.

As the data indicate, the safety risks associated with rollover accidents in large buses are not limited to only traditional motorcoaches (over-the-road buses). Thus, the agency proposes to apply the proposed requirements in today’s NPRM to buses other than those called “motorcoaches” in MAP-21. Beyond the “over-the-road” buses identified by MAP-21, NHTSA proposes to apply the proposed requirements to generally the same universe of vehicles to which the seat belt final rule applies. The agency believes that the proposed rule should apply to all buses with similar rollover crash risks.

Buses Other Than Over-the-Road Buses With a GVWR Between 4,536 and 11,793 kg (10,000 and 26,000 lb)

On the other hand, buses with a GVWR between 4,536 and 11,793 kg (10,000 and 26,000 lb) do not have the same rollover crash risks as the aforementioned bus categories. Thus, while comment is requested on this subject, this NPRM tentatively has not included these buses in today’s proposal. According to the FARS 2000–2009 data files, there were 42 occupant fatalities in crashes involving cross-country buses, other buses, and unknown buses with a GVWR between 4,536 and 11,793 kg (10,000 and 26,000 lb) in this 10-year period (see Table 5, *supra*). Among these 42 occupant fatalities in buses with a GVWR between 4,536 and 11,793 kg (10,000 and 26,000 lb), 24 fatalities were a result of 13 rollover crashes. Thus, over the ten year period between 2000 and 2009, buses with a GVWR between 4,536 and 11,793 kg (10,000 and 26,000 lb) were associated with an average of 1.3 rollover crashes per year and 2.4 fatalities per year. In contrast, there was an average of 3.2 rollover crashes among buses in these same categories with a GVWR greater than 11,793 kg (26,000 lb) per year. These crashes resulted in an average of 11.4 fatalities per year. Among all fatalities occurring in rollover crashes in cross-country, other, and unknown buses with a GVWR greater than 4,536 kg (10,000 lb), 83

⁴¹ Transit buses, school buses, and perimeter-seating buses would be excluded from the standard under this latter category.

⁴² As described further, below, over-the-road buses include buses operated by public transit agencies so long as they meet the over-the-road bus definition (buses characterized by an elevated passenger deck located over a baggage compartment).

⁴³ Except transit buses, school buses, and perimeter seating buses

⁴⁴ See Moving Ahead for Progress in the 21st Century Act, Pub. L. 112–141, § 32703(b).

percent are in buses with a GVWR greater than 11,793 kg (26,000 lb).

Further, the agency notes that buses with a GVWR between 4,536 and 11,793 kg (10,000 and 26,000 lb) are frequently used for demand-response transit⁴⁵ services.⁴⁶ These demand-response transit service vehicles are used in urban areas and rarely operate at highway speeds, which are the speeds at which the majority of bus rollover fatalities occur. Compared to the estimated number of large buses sold annually (approximately 2,200 buses), there are approximately 14,600 buses with a GVWR between 4,536 and 11,793 kg (10,000 and 26,000 lb) produced annually.⁴⁷ Given that more of the lower weight buses are manufactured than large buses annually, applying the proposed rule to buses with a GVWR between 4,536 and 11,793 kg (10,000 and 26,000 lb) may increase the potential costs of the rule more than the potential benefits.

However, NHTSA requests comment on the issue and invites useful data, particularly related to the cost of applying the proposed rule to buses with a GVWR between 4,536 and 11,793 kg (10,000 and 26,000 lb). Are there data as to whether the cost of applying the proposed requirements to buses with a GVWR between 4,536 and 11,793 kg (10,000 and 26,000 lb) will be significantly different when compared to buses with a GVWR greater than 11,793 kg (26,000 lb)? We request data that show whether the effectiveness of the countermeasures would be different between these two bus sizes. Are there data which show how the impact on small businesses would change if the requirements of today's proposal were extended to buses with GVWR between 4,536 and 11,793 kg (10,000 and 26,000 lb)?

Although the aforementioned data show that buses with a GVWR between 4,536 and 11,793 kg (10,000 and 26,000 lb) have historically been associated with less fatalities than buses with a GVWR above 11,793 kg (26,000 lb), the agency notes these buses represent a significant number of bus sales, have a lower price (\$50,000–\$65,000), and

higher fuel economy.⁴⁸ As smaller buses can also be utilized to service similar routes as larger buses, it may be possible, in the future, that more crashes could occur in these types of buses if these buses experience higher sales volume and begin to service routes that result in a higher number of vehicles miles traveled. NHTSA recognizes that this proposal does not cover all the vehicles recommended by the NTSB in recommendations H-10-3 and H-10-4. As mentioned above, the NTSB recommended that NHTSA should include all vehicles with a GVWR of 4,536 kg (10,000 lb) or greater in our rulemaking. Thus, the agency is requesting comment on the above concerns.

Transit, School, Perimeter Seating, Prison, and Double-Decker Buses

While (in general) the agency proposes to apply the requirements in this NPRM to over-the-road buses (regardless of GVWR) and other buses with a GVWR greater than 11,793 kg (26,000 lb), the agency has considered various (more specialized) types of buses and whether or not these specific types of buses should be covered by the proposed requirements. Comments are requested on each of the following bus types and whether or not the agency should apply the proposed requirements in this NPRM to these bus types.

Transit Buses

In today's proposal we have not included transit buses as a bus category that would be subjected to today's proposed requirements. The data show that the crash risk for transit buses (i.e., buses with a stop-request system that is sold for public transportation) is much lower than for the other bus types covered by today's proposal. In order to exclude transit buses, we propose to utilize the same definition for transit buses as in the seat belt final rule.⁴⁹ Our reasoning, like in the seat belt final rule, is that there is a significantly lower crash risk for passengers of transit buses. We believe this difference in crash risk is due in part to the stop-and-go manner of transit bus operation. The FARS data from 2000–2009 show that, for all bus body types with a GVWR greater than 11,793 kg (26,000 lb), transit buses have the fewest fatalities at 8.2 percent or 23 out of a total of 281. These same data show that there were 20 fatal crashes involving occupants of urban transit buses, resulting in

fatalities of 11 drivers and 12 were passengers. Thus, fatal transit bus crashes involve about one fatality, on average. In summary, there are many fewer total fatalities and fatalities per crash for transit buses, and thus a significantly lower risk than in the other buses covered by today's proposed rule.

Like in the seat belt final rule, today's proposal explicitly states that over-the-road buses cannot qualify as transit buses (and be exempt from proposed requirements). While the agency acknowledges that state and local public transit agencies may purchase an over-the-road bus and equip such buses with a stop-request system, the agency believes that over-the-road buses used by transit agencies will likely be used in a similar manner as over-the-road buses purchased by private companies (i.e., for intercity transport carrying large numbers of passengers, over long distances, and at highway speeds). It is not uncommon to see commuter express buses traveling on the highway alongside privately-operated tour and charter buses of nearly identical construction. Thus, given the overall similarity of the buses in construction and use, we cannot distinguish, from a public safety standpoint, good reasons for distinguishing privately-operated versions of the over-the-road buses from those operated by state and local public transit agencies. Comments are requested on this topic.

School Buses

As described in greater detail below, FMVSS No. 220 establishes roof strength requirements for school buses. While there are several reasons why the agency is proposing to use an ECE R.66-based test in today's NPRM, the agency is not proposing to alter the requirements for school buses. As further described below, there are various differences in the operating conditions the large buses covered under today's proposal and school buses covered under FMVSS No. 220 that make an ECE R.66-based test more suitable for the buses covered in today's proposal. As the safety record for school buses demonstrate that FMVSS No. 220 continues to be appropriate for those buses, the agency is not proposing to include school buses in today's proposal or to alter the requirements for school buses under FMVSS No. 220.

Buses With Perimeter Seating

In the seat belt final rule, the agency did not apply the seat belt requirements to buses with perimeter seating (unless the bus with perimeter seating qualifies as an over-the-road bus). We propose to do the same for the requirements in

⁴⁵ Public transportation characterized by flexible routing and scheduling of small/medium vehicles operating in shared ride mode between pickup and drop-off locations according to passenger needs. It includes transporting persons with special mobility needs.

⁴⁶ Evaluation of the Market for Small-to-Medium Sized Cutaway Buses, Federal Transit Administration Project #: ML-26-7208.07.1, December 2007, available at <http://www.fta.dot.gov/documents/AnEvaluationofMarketforSmalltoMediumSizedCutawayBuses.pdf>.

⁴⁷ See *Id.*

⁴⁸ See *Id.*

⁴⁹ Transit bus means a bus that is equipped with a stop-request system sold for public transportation provided by, or on behalf of, a State or local government and that is not an over-the-road bus.

today's NPRM. While buses that qualify as over-the-road buses (under MAP-21) are covered under today's proposal regardless of seating configuration,⁵⁰ we tentatively believe that it is appropriate to exclude perimeter buses that are not over-the-road buses because these buses with perimeter seating are used to carry people for a relatively short period, typically are meant to transport standees, and are spacious to accommodate baggage and other carry-on items and to maximize the speed of passenger boarding and alighting. Under these conditions, buses with perimeter seating are not expected to transport passengers for a long distance at relatively high speeds where rollover crashes are more common. However, the agency requests comment on whether it is likely that buses with a GVWR greater than 11,793 kg (26,000 lb) would be configured with perimeter seating and whether such buses would be used in conditions where rollover crashes are more likely to occur. We further request comment on whether such buses should be included as a bus type subject to this proposal.

Prison Buses

While prison buses were excluded from meeting the requirements of the seat belt final rule, we have tentatively decided not to exclude prison buses from the proposed requirements of today's NPRM. In the seat belt final rule, the agency noted in response to comments that certain structural aspects of prison buses (e.g., fiberglass or stainless steel low-back seats or benches) are not conducive to install seat belts. Further, we noted the security concern that lap/shoulder belt equipment could pose hazards as the buckle hardware and belt webbing could be used as weapons or tools. However, these similar concerns are not present when considering the proposed requirements in today's NPRM.

Designing the roof of a prison bus to better withstand an impact during a rollover crash is unlikely to involve any equipment that needs to be installed on the passenger seats or any equipment that could be potentially used as weapons/tools. However, the agency requests comment on whether or not it is reasonable to exclude prison buses from the proposed requirements in this rulemaking. If the recommendation is to exclude prison buses, what is the rationale for doing so? Is it reasonable

to exclude prison buses from all of the requirements proposed in this NPRM or would it be appropriate to apply some—but not all—of the requirements proposed (e.g., emergency roof exit requirements but not the survival space requirements)?

Double-Decker Buses

The agency notes that the requirements of ECE R.66 do not apply to double-decker buses while NHTSA's proposal does not exclude them from rollover structural integrity requirements.

We have tentatively decided that the proposed test procedure is not appropriate for and should not be applied to the upper/open section of open-top double-decker buses because there would be no structure to intrude into any defined survival space in the upper/open level. However, we believe that lower/enclosed sections of such vehicles (or the upper/enclosed section of a double-decker bus) can still be tested under the proposed test procedure for compliance with the requirements of the proposed rule. In the lower/enclosed or upper/enclosed level, there would be vehicle structure that could intrude into the survival space in the same fashion as a traditional bus that does not have an open-top. Comments are requested on any technical reasons that would preclude the proposed test from being applied to the enclosed section of double-decker buses, and on whether additional provisions in the regulatory text are needed in order to further account for testing of double-decker buses.

c. Test Procedure

The agency proposes in today's NPRM that compliance with the proposed performance requirements will be measured by NHTSA⁵¹ using a test substantially patterned after the complete vehicle test of ECE R.66. Similar to the ECE R.66 complete vehicle test, the proposed test would

specify that the vehicle is placed on a raised platform that is 800 mm (31.50 inches (in)) above a horizontal, dry and smooth concrete ground surface. The test would allow NHTSA to position the vehicle such that either side (right and left) of the vehicle may be tested for compliance. The tilting platform would be raised, on one side, at a rate not to exceed 5 degrees/sec along an axis no greater than a 100 mm horizontal distance from the edge of the impact surface closest to the tilting platform and 100 mm below the top of the platform surface, until the vehicle becomes unstable and commences the rollover. The tilting platform would be equipped with wheel supports to maintain the vehicle's position on the tilting platform before the vehicle becomes unstable and commences the rollover.

Ballasts Representing Restrained Occupants

To simulate a real-world rollover, the agency believes it would be appropriate to subject the vehicle to the forces resulting from the mass of restrained occupants. To achieve this, this NPRM proposes that a mass of 68 kg (150 lb) be secured in each designated seating position equipped with a seat belt system. The ballast would have to be restrained in such a manner that the ballast does not break away during the test. The 150-lb ballast would represent the mass of an "average" occupant at each designated seating position. (The 150 lb value is used in determining the vehicle's gross vehicle weight rating in accordance with 49 CFR Part 567, "Certification.")

The agency believes that ballasting is important because it increases the weight and raises the center of gravity of the vehicle to simulate the forces upon the vehicle structure in a rollover crash when the seats are occupied by restrained passengers. Also, when occupants are belted into the vehicle, their mass imparts crash forces to the seat anchorages during a crash.

While the agency believes that ballasting is important, we have tentatively concluded that the method of ballasting and type of ballast used is not important because these factors will not significantly alter the forces upon the vehicle structure or the seat anchorages during compliance testing, so long as the ballast is 150 lb. We note that ECE R.66 does specify the option of using two different occupant ballasts: anthropomorphic ballasts (commercially available "water dummies"), and fixed steel plates. The ECE regulation stipulates that if the ballast is an anthropomorphic ballast, it is secured

⁵⁰ In order to cover all the buses that were covered under MAP-21, this proposal specifically defines "perimeter seating buses" as buses that are not over-the-road buses. Therefore, over-the-road buses are covered under today's proposal without regard to their seating configuration.

⁵¹ As with all the FMVSSs, this standard would not require vehicle manufacturers to use the test to certify their vehicles. They may certify their vehicles using other means. Manufacturers must ensure, however, that their vehicles will meet the FMVSS requirements when tested by NHTSA when we use the test procedure specified in the FMVSS. If the vehicle does not meet the requirements when tested by NHTSA, we will ask the manufacturer for the basis for its certification. If the agency is satisfied that the manufacturer exercised due care in making the certification, the agency may decide not to pursue civil penalties against the manufacturer for the failure of the vehicle to comply. The manufacturer is still subject to the requirements of the National Traffic and Motor Vehicle Safety Act to recall the noncomplying vehicles and remedy the noncompliance free of charge.

using a seat belt restraint, and if the ballast is a rigid weight it is securely attached to the seat frame.

In its research, NHTSA tested both ballasting methods from ECE R.66 and the results did not show a significant difference between these methods in terms of the effect on test results. We tentatively believe that the test results of the complete vehicle rollover test will not be significantly altered so long as a 150-lb ballast is secured to each designated seating position equipped with the seat belt system. We recognize that the center of gravity of the ballast can vary depending on the manner in which it is secured to the seat and the type of ballast it is. However, as explained below, the agency tentatively believes that the difference in the ballasts will not significantly alter the loads applied to the vehicle structure (as a whole) or to the seat anchorages.

We analyzed the effect of the different center of gravity heights for the anthropomorphic ballasts and the fixed weight ballasts and found that the overall center of gravity of the vehicle—and, consequently, the energy absorbed in the rollover structural integrity test of the fully loaded vehicle—is only slightly higher (less than 3 percent higher)⁵² when using anthropomorphic ballasts as opposed to when using fixed weights as ballasts positioned on the seat cushion. We believe that this difference in the stringency of the rollover structural integrity test using different ballasts is small and within the

overall accepted variability in the test procedure.

Further, we analyzed the forces and moments generated at the anchorages due to the ballasts during the rollover impact sequence and found that the difference in moment at the anchorages due to the loading from the fixed weight ballast and that from the anthropomorphic ballast during impact is approximately 350 Nm.⁵³ This value is small in comparison to the moments at the seat anchorages due to the 3,000 lb loads on the belts in an FMVSS No. 210 test (approximately 20,000 Nm). Further, the agency tentatively believes that this difference in moment is small when we consider the racking forces that would be acting upon the seat anchorages as a result of the vehicle's impact on the impact surface during the rollover test. During our testing of the 1991 Prevost LeMirage using the ECE R.66 complete vehicle test, all the seats on the opposite side of impact detached from their wall mounts due to the racking of the bus side walls, even though the seats were not ballasted. Therefore, we have tentatively concluded that the type of ballast does not have significant effect on the performance of the seat anchorages or the vehicle structure during the rollover structural integrity test.

Nonetheless, comments are requested on our tentative conclusion. Should the agency specify a type of ballast? If so, which types of ballasts should the agency choose and what specifications are necessary? What repeatable method should the agency establish for mounting the ballast to each designated seating position? If anthropomorphic dummies from ECE R.66 are recommended, the agency requests comment on the availability of the anthropomorphic (water dummy) ballasts in the U.S. What substances can be used to fill anthropomorphic ballasts such that the ballast would achieve a weight of 150 lb with a consistent center of gravity? We note that the anthropomorphic (water dummy) ballasts specified in ECE R.66 were plastic containers (constructed to simulate the torso shape of a passenger) with the capacity to be loaded to a weight of 176 lb (80 kg). Are

anthropomorphic ballasts available which are designed to hold 150 pounds?

Separately, NHTSA has tentatively concluded that two aspects of the ballasting options allowed in the ECE R.66 complete vehicle test are not appropriate for application in our proposed test procedure.

First, we note that ECE R.66 specifies different weights depending on the type of ballast that is used during the test. The ECE regulation requires that, when anthropomorphic ballasts are used, the entire estimated weight of an individual occupant's mass of 68 kg (150 lb) is required. However, when fixed ballasts are used, only 50 percent of the estimated individual occupant's mass (34 kg (75 lb)) should be attached. The agency tentatively concludes that securing only 50 percent of the individual occupant's mass when using rigid weights would underestimate the load that will be placed on the vehicle and its seat anchorages during a rollover crash.

We note that an Australian study⁵⁴ estimated that 93 percent of a lap/shoulder belt restrained occupant mass, 75 percent of a lap belted occupant mass, and 18 percent of an unrestrained occupant mass are effectively coupled to the vehicle structure during rollover. In addition, a European Commission sponsored study⁵⁵ found that the percentage of occupant mass coupled to the vehicle structure during rollover is 90 percent for lap/shoulder belted occupants and 70 percent for lap belted occupants. Based on the above research findings, the agency tentatively concludes that the vehicle should be ballasted to the full weight of 68 kg (150 lb) at all seating positions regardless of ballast method. Using a lower weight ballast for the fixed ballast setups does not appear to adequately simulate the loading conditions of the average restrained occupant.

Second, ECE R.66 requires the rigid weight be fixed to the seat such that its center of gravity aligns with that of the anthropomorphic ballast (approximately 100 mm forward and 100 mm above the seating reference point). In our research, the agency found it difficult to position and fix the rigid weights according to this specification in a consistent and repeatable manner.

Given that difficulty, we investigated whether affixing the rigid weights as specified by ECE R.66 is necessary. It

⁵² The effect of ballasts (and the type of ballast) is greatest for the lowest weighing vehicle to which the rollover test applies, which is, by definition, a vehicle with a GVWR of 26,001 pounds. For determining the effect of the ballasts and type of ballasts, the following estimations were made: The unloaded weight of the 55 occupant motorcoach is 26,001 pounds, the center of gravity of the unloaded motorcoach is 1.22 m (48 in) above ground, the height of the seat cushion of seats in the bus is 1.5 m (60 in) above ground, and the height of the center of gravity of a 68 kg rigid weight and that of an anthropomorphic ballast in the vehicle seat is 1.57 m (62 in) and 1.7 m (67 in) above ground, respectively. The addition of a 68 kg ballast at each of the 55 seats increases the weight of the vehicle by 32 percent. The center of gravity height above ground of the fully loaded vehicle is higher than that of the unloaded vehicle by 7 percent when rigid weights are used and by 9.5 percent when anthropomorphic ballasts are used. Through film analysis of the motorcoach rollover tests, we estimated that the center of gravity of the unloaded motorcoach drops approximately 0.85 m during the test. We then estimated that the total energy absorbed by the fully loaded motorcoach ($=9.81 \times \text{total mass (kg)} \times \text{drop in center of gravity during the rollover test}$) is 3 percent greater when anthropomorphic ballasts are used than when rigid weights are used. Since the effect of ballasts is greatest for the 26,001 lb GVWR motorcoach, the difference in the center of gravity height and the energy absorbed for different ballast types will be significantly less than 3 percent for motorcoaches with a GVWR more than 26,001 lb.

⁵³ Assuming that the ballast is fully coupled to the seat, the moment at the seat anchorages generated by the ballast is equal to the product of the mass of the ballast, its acceleration, and the height of the ballast center of gravity. In the agency's three ECE R.66 tests, the peak motorcoach floor acceleration was approximately 4 gs and since the seat is fully coupled to the floor, we estimated the ballast acceleration to be 4 gs. Thus the moment generated at the seat anchorages was calculated to be approximately 350 Nm ($= 68 \text{ kg} \times 4 \times 9.81 \times (1.7\text{m}-1.57\text{m})$).

⁵⁴ Anderson, J., et al., "Influence of Passengers During Coach Rollover," Cranfield Impact Centre Ltd., ESV Proceedings, Nagoya, Japan, Paper No. 216, 2003.

⁵⁵ Enhanced Coach and Bus Occupant Safety (ECBOS), Project No. 1999-RD.11130, European Commission, 5th Framework, August 2003.

appears that the answer is no. As mentioned above, we analyzed the effect of the different center of gravity heights for the anthropomorphic ballasts and the fixed weight ballasts and found that the difference in center of gravity would not significantly affect the overall performance of the vehicle in the rollover test. Thus, assuming that steel ballasts similar to those allowed in ECE R.66 are specified in the final rule, the agency tentatively concludes that it would be sufficient to locate the steel ballasts on top of the seat cushion, since loading fixed ballasts to match the center of gravity of anthropomorphic ballasts present significant logistical challenges, without a noteworthy difference in the stringency of the test.

Vehicle Conditions

To better ensure consistent and repeatable results, the proposed test procedure also includes specifications for various vehicle conditions. The proposed test specifies that the vehicle suspension is blocked to its normal riding position and that the vehicle tires are inflated to the manufacturer's recommended tire pressure. The proposed procedure also specifies that vehicle windows, doors, and emergency exits are fully closed and in the latched but unlocked positions. All fluids in the vehicle, including fuel, will be at maximum capacity. For environmental and test personnel safety, substitute fluids would be permitted provided the weight of the original fluid is maintained.

The agency recognizes that vehicle fluids have the potential to add weight to the test specimen. As such, we request comment on whether there are certain vehicle fluids whose levels should not be included in the specifications for test conditions.

d. Survival Space

To reduce unreasonable safety risks due to inadequate structural integrity during a rollover, the agency is proposing to set minimum standards for the structural integrity of the occupant compartment. We are proposing to define a volume of space in the occupant compartment (called the "survival space") and require that there shall be no intrusion of the survival space by any part of the vehicle or by the impact surface during movement of the tilting platform or resulting from impact of the vehicle on the impact surface.

The agency is concerned that inadequate survival space may result in restrained occupants being injured by collapsing sidewalls, roof structure, or other objects. As the agency is currently

conducting rulemaking to potentially require seat belts on the buses covered by this proposed rulemaking, the agency is also interested in ensuring that passengers (if belted) will be protected from further danger due to collapsing vehicle structure that intrudes into the survival space. Our research of the ECE R.66 test procedure showed that structural intrusions into the survival space occurred in the MY 1991, MY 1992, and MY 2000 buses. Our observations showed that the survival space templates came into contact with the side windows in the rollover structural integrity tests with the older buses. Further, our review of the outside high-speed video of the test on the MY 2000 bus indicates that the side pillars may have collapsed and intruded into the occupant survival space.

Defining the Survival Space

The proposed rule defines "survival space" in a manner similar to ECE R.66's "residual space." However, we propose to define the survival space by establishing the boundaries of the three-dimensional space, as opposed to the ECE R.66 method of defining the boundaries through the use of transverse planes which intersect a seat reference point. Thus, this NPRM proposes to define the survival space as a three-dimensional volume with a front boundary beginning at the transverse vertical plane 600 mm in front of the forward-most point on the centerline of the front surface of the seat back of the forward-most designated seating position. The rear boundary of the survival space would be the inside surface of the rear wall of the occupant compartment of the vehicle. Comments are requested as to whether the term "occupant compartment" is clear.

The vertical boundaries on both the left and right sides of vehicle centerline are defined by three line segments (see Figure 6 below). Segment 1 extends vertically from the floor to an end point that is 500 mm above the floor and 150 mm inboard of the side wall. Segment 2 starts at the end point of Segment 1 and extends to a point 750 mm above and 250 mm horizontally inboard of the end point of Segment 1. These values are used in ECE R.66. Segment 3 is a horizontal line beginning at the end point of Segment 2 and extending to the vertical longitudinal center plane of the vehicle.

In proposing this requirement for a survival space, the agency intends to ensure that the vehicle has sufficient structural strength to ensure that the survival space during and after the rollover structural integrity test is maintained. We intend the dimensions

of the survival space to define a volume of space that vehicles with a minimally acceptable degree of structural integrity should provide. The survival space requirement would serve as another indicator of the roof and sidewall strength of the vehicle. The requirement would be a reasonable proxy through which the agency could assess the adequacy of the structural integrity of the vehicle.

The agency tentatively believes that the increased structural integrity countermeasures should be applied to substantially the entire length of the vehicle. Thus, this NPRM proposes a survival space volume which runs the length of the area that can be occupied by the driver and by the passengers. Therefore, this proposed rule defines the front boundary of the survival space as 600 mm in front of the forward-most point on the centerline of the forward-most designated seating position. Additionally, the proposed rule defines the rear boundary as the rear inside wall of the occupant compartment.

The agency proposes to set the vertical boundary of the survival space using the three line segments outlined above and illustrated in Figure 6 below. These three line segments mirror the equivalent vertical boundaries used in the ECE R.66 test. The agency tentatively believes that the vertical boundaries of the survival space from the ECE regulation are appropriate for application in this proposed rule for several reasons. The vertical boundary appears reasonably related to the occupant space. Photographs from the MY 2000 MCI test report show the location of the vertical boundary of the survival space as just about level with the top of the head of the seated HIII 50th percentile adult male test dummies in the seat. "ECE Regulation 66 Based Research Test of Motorcoach Roof Strength, 2000 MCI 102-EL3 Series Motorcoach, NHTSA No.: MY0800," October 1, 2009, *supra*. (We have also placed in the docket for this NPRM other photographs of the test dummies seated in front of survival space templates.) In addition, as increasing or decreasing the height of the vertical boundaries of the survival space could significantly alter the stringency of the rollover structural integrity test, the agency believes that there is a strong interest in maintaining similar requirements to ECE R.66 so as to reduce the regulatory burden on manufacturers having to comply with different European and U.S. standards.

Further, as all the older model buses tested by the agency were unable to

meet the survival space requirements⁵⁶ yet current vehicles in Europe are approved as meeting the requirements, the agency believes that setting the same vertical limits of the survival space increases the likelihood of the

practicability of the U.S. standard. Therefore, the agency tentatively believes that this definition of the survival space is an appropriate, practical, and practicable proxy for ensuring that the roof and sidewalls will

be able to withstand the racking forces of rollover crash.

Comment is requested on the need and basis for different boundaries for the survival space.

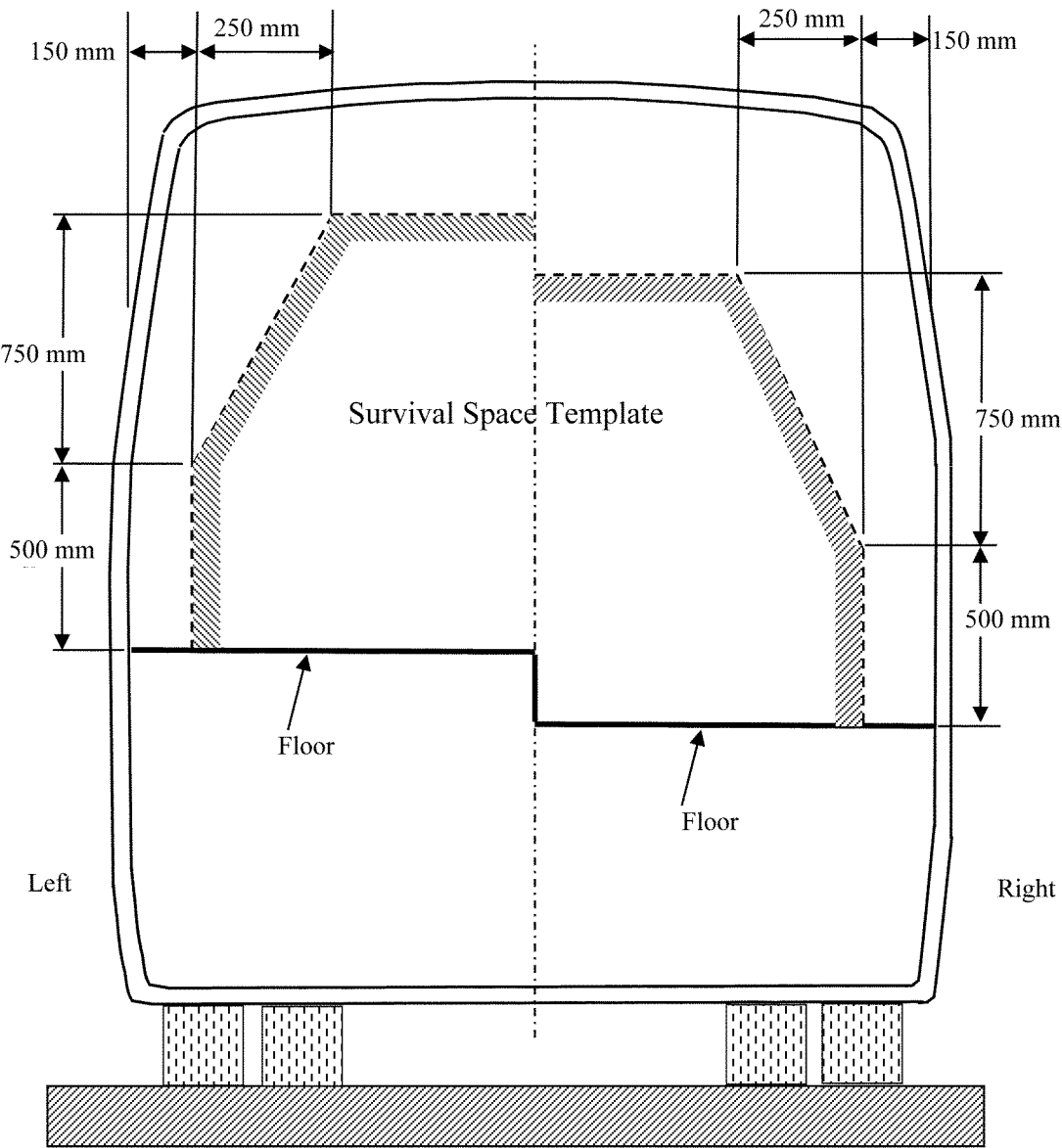


Figure 6: Survival Space Template

Determining Intrusions Into the Survival Space

The NPRM proposes to prohibit any object that is outside the survival space from entering the survival space. Comments are requested on the use of survival space templates as tools in

helping determine if there was intrusion into the survival space. Use of templates is consistent with ECE R.66. The templates are 1,250 mm (50.2 inches) tall and are tapered from the sidewall a distance of 150 mm (5.9 inches) at the

bottom and 400 mm (15.8 inches) at the top.

We anticipate using several survival space templates within the survival space to assist us in determining whether there was intrusion into the survival space. The templates would

⁵⁶ We note that while the survival space templates in the MY 2000 motorcoach did not come into

contact with objects outside of the survival space during the test, we observed intrusions into the

survival space separate from the survival space templates.

contain a transfer medium (such as chalk or another substance capable of demonstrating contact between two objects) along the upper edge of each template. Transfer marks from contact with the survival space templates would demonstrate that an object intruded into the survival space during movement of the tilting platform or resulting from impact of the vehicle on the impact surface.

We plan on securing the survival space templates to the vehicle floor such that they remain in their installed location during the test. We recognize, however, depending on seat placement and attachment, seats may have to be removed or shifted to accommodate the placement of the survival space templates or other testing equipment. Thus, we would move the seats forward or rearwards to make room for the equipment if the seat spacing is adjustable. If the seat spacing is not adjustable, we would remove seats from the vehicle and allow ballasts representing the weight of the seat and its occupants to be secured to the vehicle floor either forward or rearward of the original seat placement (within a specified tolerance⁵⁷). Comments are requested on these procedures.

We emphasize that the templates are simply tools to assist in determining whether there was intrusion into the survival space. If an object intruded into the survival space without contacting the templates—such as if a television monitor fell into the survival space—that intrusion could be a noncompliance, even if contact with the templates did not occur. Other tools could also be used to help determine whether there was intrusion into the survival space, such as deformable templates, high speed video, photography, or a combination of means. NHTSA could use templates and/or other means of determining whether intrusion occurred.

e. Overhead Luggage Rack and Seat Retention

The agency is proposing a retention requirement for overhead luggage racks and the passenger seats. The proposed retention requirement is that each anchorage of an overhead luggage rack or seat shall not completely separate from its mounting structure during movement of the tilting platform or resulting from impact of the vehicle on the impact surface.

The NTSB identified overhead luggage racks as a safety concern in its investigation of the Sherman, Texas bus crash. The right side overhead luggage rack anchorages completely detached from the nine brackets at the connection points and fell diagonally across the aisle onto the passengers. NTSB stated that “several passengers’ heads contacted the overhead luggage rack and, although investigators were unable to determine exactly when in the accident sequence passenger injuries took place, it is possible that serious head or neck injury resulted from the interactions between the passengers and the overhead luggage rack.”

Our research confirms the possibility of this danger. In the tests conducted by the agency, the overhead luggage rack on the older MCI bus broke, exposing sharp edges that pose a risk of injury to passengers. The overhead luggage racks did not break during testing of the newer MY 2000 MCI bus. We thus acknowledge that, while this was one test, the finding indicated a possibility that manufacturers may have made some improvements to the strength of luggage rack mounts. It also indicates the practicability of meeting the proposed requirement.

The overhead luggage rack retention requirement is an additional way of ensuring that vehicles provide a minimum level of structural integrity. The vehicle will have to limit its deformation and racking⁵⁸ in the rollover structural integrity test, to ensure that the overhead luggage racks meet the retention requirement. The requirement would also reduce the risk that overhead luggage racks could be dislodged and injure occupants or block or impede emergency egress.

The retention requirement would apply to luggage racks regardless of their position relative to the survival space. Suppose, in the rollover structural integrity test, an overhead luggage rack separates from its mounting structure and one of its anchorages completely separated from the anchorage’s mounting structure but the overhead luggage rack does not enter the survival space. We would consider that to be a failure to meet the retention requirement.

With regard to the seats in these buses, the agency is also concerned about the strength of the anchorages that secure the seats to the vehicle. The tests conducted by NHTSA revealed the possibility that seat anchorages have the potential to break and cause injury to passengers in these buses. In our test of

the MY 1991 Prevost LeMirage bus, all seat anchorages detached from their sidewall mounting anchorages and the seat with the restrained occupant completely separated from its anchorages and fell with the test dummy still attached to the seat. We acknowledge that manufacturers may have made improvements since the manufacture of that MY 1991 Prevost bus. Also, seat anchorages would likely be strengthened if these buses had to meet the requirements under development for passenger seat belts. However, the agency believes it is highly important for passenger safety that the vehicle structure limit deformation and racking of the sidewall, such that the passenger seats will remain attached to the vehicle in a rollover (particularly if passengers are restrained to the seat). It is important to ensure the structural integrity of the bus in a rollover will enable the seat anchor to withstand the load of the seat and that of the restrained occupant.

Compliance would be assessed by inspection of the component’s mounting structure. We propose to permit the anchorage to be damaged or deformed during the course of the rollover, but we would prohibit any one anchorage from completely separating with the mounting structure. A complete separation is indicative of unacceptable structural integrity.

Comments are requested as to what other items should be covered by these retention requirements (e.g., television monitors). Please provide data supporting the safety need for your suggestion. What methods are available to the agency to objectively and practicably evaluate the retention of the item?

f. Emergency Exits

The agency is not only concerned with the protection of belted occupants, but also with protecting unbelted occupants. The agency recognizes there is a possibility that not all occupants traveling in the buses covered by today’s proposal will be restrained at all times during travel. For instance, passengers may need to occasionally move about the occupant compartment during long, intercity journeys. Further, MAP-21 directs the agency to consider “portal improvements to prevent partial and complete ejection of motorcoach passengers.”⁵⁹ Thus, the agency is considering—as a part of this rulemaking—requirements that emergency exits remain latched so as to

⁵⁷ The proposed text in this NPRM limit the placement of these ballasts to no farther forward than the forward-most point of the motorcoach seat directly in front of the removed seat and no farther rearward than the rearmost point of the motorcoach seat directly behind the removed seat.

⁵⁸ The term, “racking,” means the tilting of the sides of the bus relative to the bus floor.

⁵⁹ See Moving Ahead for Progress in the 21st Century Act, Pub. L. 112–141, § 32703(b)(2).

avoid becoming an ejection portal for unrestrained occupants.

In the ECE R.66 tests conducted by the agency in support of this NPRM, the emergency roof exits of all the tested buses (new and old) opened upon impact of the bus with the impact surface. The agency is concerned that emergency roof exits may become ejection portals through which unrestrained passengers could be ejected during a rollover crash. Therefore, the agency has proposed a requirement in today's NPRM that all emergency exits shall not open during the rollover structural integrity test. While the agency has tentatively determined that this requirement (remaining closed during and after the rollover test) would be appropriate for the emergency exits, the agency also requests comments on whether other similar openings exist in the bus that could also become ejection portals in a similar fashion to emergency exits and whether they should also be subject to the proposed requirements. For example, are there other windows or roof hatches that are designed to open in buses that are not emergency exits? Do these openings have similar safety concerns?

In addition, for emergency exits, NHTSA also seeks to increase the likelihood that roof and rear door emergency exits are operable after a rollover crash.⁶⁰ Inoperable emergency exits would impede emergency egress and emergency rescue efforts. Accordingly, we have proposed to require that the emergency exits on the roof and at the rear of the bus (installed to fulfill the emergency exit requirements of FMVSS No. 217) be able to operate as required under FMVSS No. 217 after the impact. The agency tentatively concludes that these requirements are necessary to ensure that these emergency exits are operable after being exposed to the racking forces of rollover crashes.

Note that we have tentatively concluded not to apply the above requirements (that the emergency exits be operable as required under FMVSS No. 217) to side emergency exit windows. A requirement that window exits facing the impact surface must open upon application of the FMVSS No. 217 forces would not make sense, since the exits are face-down on the ground. A requirement that window exits facing the sky on the opposite side of the impact surface must open as

directed by FMVSS No. 217 might not be achievable with the vehicle on its side because of the mass of the window glazing and the effect of gravity.

g. Side Window Glazing

NHTSA proposes that, after the rollover structural integrity test, each window glazing opposite the impacted side of the vehicle shall not detach from its mounting. The purpose of the requirement is to ensure that the vehicle's structural integrity will prevent heavy glazing panels from falling into the passenger compartment and becoming ejection portals. As with our discussion of emergency exits (above), this proposed requirement to enhance side window glazing retention through structural integrity is part of NHTSA's consideration of countermeasures that would help prevent partial and complete ejection of motorcoach passengers (pursuant to the provisions in MAP-21⁶¹). NHTSA would assess compliance with this requirement by requiring that the side window opening not allow the passage of a 102 mm diameter sphere when a force of no more than 22 Newtons (N) is applied at any vector towards the exterior of the vehicle.

Our test of the MY 2000 45-foot MCI bus demonstrated that side window glazing can detach during the rollover structural integrity test and collapse into the passenger compartment. Based on an assessment conducted in the agency's research to enhance emergency evacuation (the third action item in NHTSA's 2007 Approach to Motorcoach Safety), side windows in buses can weigh as much as 84 kg (185 lb).⁶² We are concerned that increasingly massive glazing panels are increasingly difficult to retain in the mounting structure in a crash. Because the rollover structural integrity test proposed today simulates significant racking forces which can deform the window glazing mounts, we believe that adopting a test that in effect determines if the glazing remained in its mounting structure will lead to increased structural integrity on these vehicles, and a reduced risk of injury from falling panels of glazing and occupant ejections.

⁶¹ As described above, MAP-21 directs the agency to establish improved roof and roof support standards (in section 32703(b)(1)) and consider glazing and other portal improvements to prevent partial and complete ejection of passengers (in section 32703(b)(2)).

⁶² Human Factors Issues in Motorcoach Emergency Egress INTERIM REPORT 1—FINAL; John A. Volpe National Transportation Systems Center, Research and Innovative Technology Administration, August 2009. Docket No. NHTSA-2007-28793.

The 102 mm (4 in) performance limit is used in FMVSS No. 217, "Bus emergency exits and window retention and release," (49 CFR 571.217). Under that standard, in order to minimize the likelihood of occupant ejection, bus manufacturers are required to ensure that when a force is applied to the window glazing as specified in that standard, each piece of glazing and each piece of window frame be retained by its surrounding structure in a manner that prevents the formation of any opening large enough to admit the passage of a 102 mm diameter sphere under a 22 N (5 lb) force.

We tentatively conclude that the FMVSS No. 217 specification for assessing integrity of the window, based on passage of a 102 mm diameter sphere (and a force application of 22 N), is appropriate to test for window glazing remaining securely attached to its mounting at the conclusion of today's proposed test. The agency tentatively concludes that the proposed requirement specifies a minimum level of performance that better ensures that side window glazing and their mountings can withstand the racking forces associated with a rollover. As a result, occupants will be better protected from heavy window glazing that may collapse into the survival space, and from risk of ejections.

We note that section 32703(b)(2) in MAP-21 also directs the agency (when considering portal improvements that can help prevent occupant ejection) to also consider the impact of such improvements on emergency egress. We are not currently aware of any data that show that the improvements to window mounting (proposed in this section) will have a detrimental impact on emergency egress. We are not aware of any large bus fatalities that were caused by non-functioning or unavailable emergency exits (i.e., trapping occupants inside the bus).⁶³ On the other hand, the data clearly show a high correlation between occupant ejection and occupant fatality. The data also show that window glazing can become dismounted during a rollover crash and fall into the survival space where bus occupants will be. Thus, we tentatively conclude that the proposed improvements to window glazing mounting can address significant safety concerns and are

⁶³ However, as discussed in the section prior, we do propose to require that emergency exits will operate as specified under FMVSS No. 217 after being exposed to the crash conditions of the proposed test. We believe that this proposed requirement would also help alleviate any concerns that large bus occupants might be trapped in the vehicle after a crash without forgoing the important benefits of preventing occupant ejections and window glazing intrusions into the survival space.

⁶⁰ The provisions of MAP-21 also direct the agency to consider the impact of portal improvement standards on the use of motorcoach portals as a means of emergency egress. See *id.*

unlikely to produce any substantial negative impact on safety. We request comment on this tentative conclusion and whether there are any data/cases that show that improving side window mounting would lead to a negative safety impact outweighing the aforementioned safety benefits.

VI. Regulatory Alternatives

In deciding on the approach proposed in this NPRM, NHTSA has examined the following alternatives to this proposal.

a. FMVSS No. 216

NHTSA considered the requirements of FMVSS No. 216, "Roof crush resistance." FMVSS No. 216 applies to vehicles with a GVWR of 4,536 kg (10,000 lb) or less, and specifies a test that applies localized static loads to the front of the vehicle. Unlike passenger vehicles, the large buses that we propose to cover under today's NPRM are larger/heavier and are more likely to roll than yaw. As a result, in a rollover involving one of these vehicles, the entire length of the vehicle is loaded as in the ECE R.66 test. Therefore, the ECE R.66 test is more representative than the FMVSS No. 216 test since it imparts loads along the full length of the vehicle. In addition, the ECE R.66 is a dynamic test where additional safety issues specific to the vehicles covered by this rulemaking (opening of emergency exits, failure of seat and overhead luggage rack anchorages, and detachment of windows from their mountings) can be evaluated. This is not possible in the FMVSS No. 216 test since it is a quasi-static test. Since two-thirds of rollover fatalities are due to ejections, addressing these additional safety issues is critical to addressing the safety problem in rollovers. Therefore, the agency believes that the ECE R.66 test is a better representation of a large bus rollover crash than the FMVSS No. 216 test. Thus, the agency has tentatively chosen not to include a test based on FMVSS No. 216 in today's NPRM.

b. FMVSS No. 220

FMVSS No. 220 is a school bus roof crush standard which places a uniformly distributed vertical force pushing directly downward on the top of the bus with a platen that is 914 mm (36 inches) wide and that is 305 mm (12 inches) shorter than the length of the bus roof. The standard specifies that when a uniformly distributed load equal to 1.5 times the unloaded vehicle weight is applied to the roof of the vehicle's body structure through a force application plate, the downward

vertical movement at any point on the application plate shall not exceed 130 mm (5.125 inches) and the emergency exits must be operable during and after the test.

The agency included FMVSS No. 220 in its research into rollover structural integrity for large buses. However, we have tentatively decided to propose a test based on ECE R.66 rather than a test based on FMVSS No. 220 for several reasons. First, the agency believes that an ECE R.66 based test is more suitable for the vehicles covered by this proposed rule than an FMVSS No. 220 based test because a significant portion of fatalities in these rollovers result from occupant ejections. Unlike school buses, these large buses operating intercity routes typically travel at higher speeds than school buses transporting children to a local educational facility. Further, many of these buses are designed such that they have a higher center of gravity than school buses and utilize larger windows. These characteristics can lead to a higher incidence of occupant ejections during rollovers involving these types of buses. Thus, the dynamic rollover test in ECE R.66 affords the agency the opportunity to better evaluate ejection mitigating factors such as the emergency exits and side window glazing retention during a rollover crash.

In addition, the vehicles covered by this proposed rule generally have more interior fixtures (such as luggage racks) than school buses and the data show that such interior fixtures have, at times, failed and created dangerous conditions. Again, the dynamic nature of the ECE R.66 protocol provides an opportunity to assess the strength of these internal fixtures, which have been identified as a safety concern in these types of vehicles.

Second, ECE R.66 is an existing test, designed specifically to evaluate the performance of this vehicle type in rollover crashes. NHTSA has greater assurance (than with an FMVSS No. 220 based test) that this proposed standard can be applied to the large buses covered by today's proposal. Further, by basing our proposed test on ECE R.66, we believe that manufacturer familiarity with the proposed standard would help reduce many uncertainties in compliance. In addition, in the absence of data showing ECE R.66 should be preferred less than an alternative, the ECE R.66 based test proposed by today's NPRM is also merited because it allows the agency to further its harmonization efforts with the European Union.

Due to these differentiating characteristics, the agency believes that ECE R.66 is more suited than FMVSS

No. 220 for evaluating rollover structural integrity in the large bus types covered by today's proposal. Since FMVSS No. 220 is a quasi-static test, it also does not address the additional safety issues specific to these bus types. While FMVSS No. 220 has a proven record of ensuring rollover safety in school buses, it was not designed for the purpose of evaluating rollover crash performance of the buses that are the subject of today's proposal. Therefore, today's NPRM proposes a test based on ECE R.66.

c. ECE R.66 Alternative Compliance Methods

The proposed test in today's NPRM is based on the complete vehicle test from ECE R.66. In addition to the complete vehicle test, ECE R.66 provides manufacturers four alternative options for complying with ECE R.66 requirements.⁶⁴ The following options are considered by ECE R.66 to be equivalent approval tests: (1) Rollover structural integrity test of body sections representative of the vehicle, (2) quasi-static loading tests of body sections, (3) quasi-static calculations based on testing of components, and (4) computer simulation (finite element analysis) of complete vehicle.⁶⁵

The agency has considered these alternative compliance methods but has determined they would not be practical for the agency's compliance testing.

We have tentatively determined that Alternatives 1 and 2 would not be practical for use by the agency as they would not achieve the goals of this rulemaking. These alternative methods test body sections of the vehicle. The alternatives pose compliance difficulties. If NHTSA were to use Alternatives 1 and 2, the agency would likely have to acquire materials and information supplied from the manufacturers, or "section" the vehicle ourselves, which is impractical.

⁶⁴ There are significant differences in the manner in which a manufacturer demonstrates compliance with safety regulations in European Union and in the United States. In Europe, European governments use "type approval," which means that they approve particular designs as complying with their safety standards. In the U.S., NHTSA issues performance standards, to which manufacturers self-certify that their vehicles or equipment comply. NHTSA does not pre-approve vehicles or equipment before sale. Under the National Traffic and Motor Vehicle Safety Act, the FMVSSs must be objective, repeatable, and meet certain other statutory criteria. NHTSA enforces the FMVSSs by obtaining vehicles and equipment for sale and testing them to the procedures specified in the FMVSSs.

⁶⁵ Further information regarding the alternative certification methods of ECE R.66 is available at: Motorcoach Roof Crush/Rollover Testing Discussion Paper, March 2009, Docket No. NHTSA-2007-28793-0019.

Alternatives 1 and 2 require that the body-sections be representative of the entire vehicle. Determining the representativeness of a body-section would require input and analysis from the manufacturer, and even with that, determining what is “representative” could be subjective and difficult for NHTSA to verify. (E.g., is the center of gravity of the body section representative of the whole vehicle?) Also, testing an entire vehicle rather than body sections is preferable to us because it would better ensure the assessment of all body sections, including representative as well as worse-case (weakest) sections of the bus. Also, if manufacturers were to provide the test specimens, a more conscientious effort might be taken by them to manufacture the specimen, and so the specimen might not be representative of the typical, mass produced bus. Thus, we prefer not to involve manufacturer-supplied body sections in NHTSA’s compliance test.

Alternatives 3 and 4, above, would not be suitable for incorporation into the FMVSS for NHTSA’s compliance testing because they may not be sufficiently objective. NHTSA is directed to issue performance standards,⁶⁶ the compliance with which must be measured objectively.⁶⁷ Assessing compliance using calculations and extrapolations or computer simulations introduces an element of subjectivity into the compliance process. A manufacturer might believe that its vehicle met the structural integrity requirements based on its calculations and computer simulations, while someone else might not agree that the assumptions made in the calculations or on which the simulations were based were appropriate or correct for demonstrating compliance in the particular instance. While a manufacturer may have the knowledge of the materials and joint structure for their vehicles to be able to make a more accurate model, an external entity may not be able to easily reproduce these results. The variability of assumptions in such models makes this method unsuitable for use by NHTSA in evaluating compliance with an FMVSS.

⁶⁶ In 49 U.S.C. 30102, the National Traffic and Motor Vehicle Safety Act defines “motor vehicle safety” as the “performance” of motor vehicles or motor vehicle equipment in a way such as to avoid creating an unreasonable risk of accident to the general public. The same Act defines “motor vehicle safety standards” as minimum standards for motor vehicle or motor vehicle equipment “performance.”

⁶⁷ In 49 U.S.C. 30111 (a), the National Traffic and Motor Vehicle Safety Act requires that Federal motor vehicle safety standards be stated in objective terms.

For example, for Alternative 3, we would need to identify the location of the plastic zones and plastic hinges as well as estimate their load-deformation curves. For Alternative 4, mathematical models that simulate accurately the actual rollover crash of the vehicle are required.

Moreover, basing compliance on calculations and computer simulations does not take into account any differences that may occur between the analytical model and the vehicle as manufactured. Because they do not utilize an actual vehicle, these approaches do not account for variation or flaws in material properties, or defects or errors in the manufacturing build processes. In contrast, NHTSA prefers to test actually-manufactured vehicles, to assess not only the design of the vehicle but the real-world manufacturing processes as well.

For these reasons, today’s NPRM is based on the complete vehicle test of ECE R.66 and does not provide for NHTSA’s use of Alternatives 1 through 4 to determine compliance.

d. Comments Requested on Alternative Levels of Stringency

As stated above, we believe that the ECE R.66 test is the most appropriate test for addressing the safety concerns related to the large buses covered under this NPRM. However, we request comment on potential alternative levels of stringency that could be used with this test. In this NPRM, we propose to use essentially the same survival space requirements as in ECE R.66. The agency is aware of research that supports the stringency levels adopted by ECE R.66⁶⁸ and (absent any data to the contrary) the agency believes that

⁶⁸ A 2007 paper by Matolcsy reported on different types of rollover tests and a comparison of these tests to real world bus rollover events. The type of tests considered were a bus rolled down a 5.5 to 9 meter high embankment with two different grades (which would result multiple rolls of the bus) and the ECE R.66 type tip-over test from an 800 mm platform on to a concrete surface (proposed in this document). Matolcsy found that the loads on the superstructure in the ECE R.66 were greater than those in the rollover tests down various grades of embankments. A reinforced bus superstructure that maintained its occupant survival space in the rollover test down a steep embankment performed poorly in the ECE R.66 test and needed further reinforcement. Matolcsy also presented real world rollover accidents involving buses designed to comply with ECE R.66 requirements and where the occupant survival space was not compromised. In one such accident, the ECE R.66 compliant bus rolled down a 9–10 meter high embankment with a 30–35 degree grade and completed 2 and 1/4 turns without compromising its survival space. See Matolcsy, M., “The Severity of Bus Rollover Accidents,” Scientific Society of Mechanical Engineers., ESV Proceedings, Lyon, France, Paper No. 07–0989, available at <http://www-nrd.nhtsa.dot.gov/pdf/esv/esv20/07-0152-O.pdf>.

there is value in adopting a standard that is as harmonized with the EU as possible.

Thus, while we propose to adopt the survival space requirements specified in this document (which are essentially the ECE R.66 requirements) we request comment on whether there is any data to indicate what the marginal benefits and costs would be for increasing or decreasing the survival space requirements. In other words, what other potential levels of stringency could the agency consider (i.e., larger or smaller survival spaces) and what data would support choosing that level of stringency? What would the safety impact be for that different level of stringency and how would the costs be different? What other types of adjustments in stringency should the agency consider? For example, should the agency consider adjusting the height of the platform used to tilt the bus during the test? This type of change could increase or decrease the severity of the bus’ impact during the test.

In addition, we note that our proposal includes additional performance requirements on the integrity of the luggage racks, seats, and window glazing attachments. As we stated, we believe these requirements are complementary to the survival space requirements. However, we acknowledge that these requirements make the proposal slightly more stringent than the ECE R.66 requirements. These additional performance requirements were included in the proposal because of observed failures of bus components that resulted in occupant injuries in real world bus rollover crashes or had the potential for injuring occupants. We seek comment on these additional performance requirements in the proposal over those specified in ECE R.66. Are there additional requirements that the agency should consider for this test? We also seek comment on whether the agency should remove these additional performance requirements from the proposal and thereby making the test slightly less stringent.

VII. Other Issues

a. Retrofitting

The Secretary of Transportation has authority to promulgate safety standards for “commercial motor vehicles and equipment subsequent to initial manufacture.”⁶⁹ The Office of the Secretary has delegated authority to NHTSA to “promulgate safety standards

⁶⁹ Under Sec. 101(f) of Motor Carrier Safety Improvement Act of 1999 (Pub. L. 106–159; Dec. 9, 1999).

for commercial motor vehicles and equipment subsequent to initial manufacture when the standards are based upon and similar to a [FMVSS] promulgated, either simultaneously or previously, under chapter 301 of title 49, U.S.C.”⁷⁰ Further, § 32703(e)(2) of MAP-21 states that the “Secretary may assess the feasibility, benefits, and costs with respect to the application of any requirement established under subsection . . . (b)(2) to motorcoaches manufactured before the date on which the requirement applies to new motorcoaches.”⁷¹ Subsection (b)(2) directs the agency to consider partial improvements to prevent partial and complete ejection of motorcoach passengers.

Based on our testing of the MY 1991 Prevost and the MY 1992 MCI buses, the agency believes that major structural changes to the vehicle’s entire sidewall and roof structure would be needed for some existing buses to meet the rollover structural integrity requirements proposed in today’s NPRM. The agency is concerned that such extensive modifications may not be possible on all existing vehicles that would be covered by this proposed rule if the scope were expanded to include retrofitting requirements. In addition, we expect these major structural changes to carry significant additional costs beyond those estimated in our regulatory analysis, and possibly have a substantial impact on a significant number of small entities (e.g., owner-operators of large buses used for transport).

In regards to the proposed requirements for side window glazing retention and emergency exits, the agency also believes that major structural changes would be necessary to ensure a comparable level of performance (when compared to a new large bus manufactured to meet today’s proposed requirements). As emergency exits and side window glazing can create ejection portals during a rollover crash due to the structural deformation that can occur during a crash, the extensive modifications to the bus structure that would be necessary for enhanced side window glazing retention and emergency exit performance may also not be possible. Thus, the agency has tentatively concluded that requiring

retrofitting of existing buses would be impracticable and NHTSA has tentatively decided not to include retrofitting requirements in today’s NPRM.

The agency seeks comment on these tentative conclusions. The agency notes that the service life of a bus can be 20 years or longer and that it is possible that the cost of retrofitting can vary substantially depending on the requirements being applied to used buses and the countermeasures available. Further, we note that the proposed “complete vehicle” test of ECE R.66 is unlikely suitable for evaluating compliance with any requirements applied to used buses (as ECE R.66 is a destructive test).

Thus, the agency seeks information on the technical and economic feasibility of a potential retrofit requirement. Which requirements in today’s proposal could be appropriately applied to used buses? What potential test procedures could the agency utilize to objectively measure compliance? Would it be reasonable to assess compliance with a retrofit requirement by means of only visually inspecting the vehicle? What lead time and phase-in issues should the agency consider for a potential retrofit requirement? What would the potential costs be?

b. Lead Time

If the proposed changes in this NPRM are made final, NHTSA is proposing a compliance date of three years after publication of a final rule. MAP-21 (in § 32703(e)) directs the agency to apply regulations prescribed in accordance with § 32703(b) “to all motorcoaches manufactured more than 3 years after the date on which the regulation is published as a final rule.” We believe that a three-year lead time after publication of final rule is appropriate as some design, testing, and development will be necessary to certify compliance to the new requirements.

Based on our research, the agency believes that manufacturers may need to make structural design changes to their new models either by changing the strength of the material or the physical dimensions of the material. In addition, the manufacturers may need to strengthen the seat and luggage rack anchorage methods, improve the type of latches used on emergency exits, and improve the mounting of side windows. Thus, the agency tentatively concludes that three years of lead time would be needed to enable manufacturers to make the necessary changes.

To enable manufacturers to certify to the new requirements as early as

possible, optional early compliance with the standard would be permitted.

c. Additional MAP-21 Considerations

In addition to the aforementioned MAP-21 provisions, MAP-21 also directs the agency to consider the best available science, potential impacts on seating capacity, and potential impacts on the size/weight of motorcoaches.⁷² Further, MAP-21 directs the agency to consider combining the various motorcoach rulemakings contemplated by MAP-21 and to avoid duplicative benefits, costs, and countermeasures.⁷³

NHTSA has considered the best available science in developing today’s NPRM. Regarding any potential impacts on seating capacity, the agency currently does not believe that the requirements proposed in today’s NPRM will require structural reinforcements at the expense of seating capacity. However, the agency requests comment on this issue.

Through today’s NPRM and its accompanying Preliminary Regulatory Evaluation (PRE), the agency is considering potential impacts on the size and weight of motorcoaches (and other large buses that would be affected by the proposed rule).⁷⁴ As described further in section VIII, *infra*, (and in the PRE) the agency has considered potential weight increase to motorcoaches as a potential cost of this proposed rule (due to increased fuel consumption). In the accompanying PRE, we have attempted to quantify and account for this potential cost (of increased fuel consumption) in our cost-benefit analysis of the rule. After considering all costs (including the potential weight increase), the agency tentatively believes that the proposed requirements in today’s NPRM would be cost-beneficial.

Further, the agency is considering combining the rulemakings contemplated by MAP-21 and avoiding the duplication of benefits/costs/countermeasures in today’s NPRM. As mentioned above, the agency believes that the proposed test (based on ECE R.66) can be used not only to evaluate the structural integrity of a large bus (such as an over-the-road bus) but also to evaluate the strength of its structural integrity in supporting side window glazing retention and emergency exit latches. As NHTSA’s research on various motorcoach models showed that (during a rollover crash) side window

⁷⁰ See 49 CFR 1.95(c). Additionally, the Federal Motor Carrier Safety Administration (FMCSA) is authorized to enforce the safety standards applicable to commercial vehicles operating in the U.S.

⁷¹ See Moving Ahead for Progress in the 21st Century Act, Pub. L. 112–141, § 32703(e)(2). Section 32703(e)(2)(B) states that the Secretary shall submit a report on the assessment to Congress not later than 2 years after date of enactment of the Act.

⁷² See Moving Ahead for Progress in the 21st Century Act, Pub. L. 112–141, § 32703(e)(1).

⁷³ See *id.* at § 32706(b)–(c).

⁷⁴ “Motorcoach” in this paragraph has the meaning given in MAP-21 (over-the-road buses).

glazings have the potential to become dislodged and emergency exits have the potential to open, NHTSA tentatively believes that the proposed ECE R.66-based test can be used to address at least part of Congress's concerns under § 32703(b)(2) (anti-ejection safety) in addition to the concerns under § 32703(b)(1) (roof strength). Thus, the agency is combining these two aspects of MAP-21 into this rulemaking proceeding.

Finally, NHTSA is avoiding the duplication of benefits, costs, and countermeasures in today's rulemaking proceeding with other potential NHTSA rules being considered pursuant to MAP-21. The agency does not believe that potential countermeasure used to meet the proposed requirements of today's NPRM would be duplicative of other rules. As described above, the agency believes that the potential requirements in today's NPRM would work hand-in-hand with the agency's final rule on seat belts. As described below in section VIII, *infra*, and the accompanying PRE, the agency is expressly considering the estimated costs and benefits of the final rule requiring seat belts on the large buses. The agency is not attributing the estimated costs and benefits of the final rule on seat belts to this rulemaking proceeding on structural integrity.

In sum, we have issued today's NPRM after careful deliberation of the factors emphasized for consideration in MAP-21, which we note are also factors NHTSA routinely investigates carefully when the agency conducts rulemaking under the Motor Vehicle Safety Act.

VIII. Overview of Costs and Benefits

Based on the FARS data over the ten year period between 2000 and 2009, there were a total of 32 fatal rollover crashes involving the large bus types covered by this proposal, resulting in 114 occupant fatalities. Beyond the benefits attributable to the rule on seat belts for these vehicles and a possible rulemaking on electronic stability control systems,⁷⁵ the agency estimates

that today's proposed rule would save approximately 3.1 equivalent lives annually if 15 percent of occupants use seat belts, and approximately 2.3 equivalent lives annually if 84 percent of occupants use seat belts.⁷⁶

While occupants that are belted will benefit from increased structural integrity, the agency believes that unbelted occupants will receive additional protection as well. The proposed rulemaking will offer the unbelted occupant additional protection through reduced risk of ejection. The belted occupant will most likely benefit mainly from reduced intrusion, and seats remaining secured. Given these potential differences in effectiveness of structural improvements for belted and unbelted occupants, the agency has estimated benefits for each group separately.

The benefits estimates also vary by seat belt use. Available research regarding seat belt use suggests that it can be highly variable and the agency has estimated the lower end of seat belt use at 15 percent and the upper end of seat belt use to be consistent with that of passenger vehicles, at 84 percent. In spite of this, the agency expects belt use, initially, to be closer to the lower end (of 15%) in part because many passengers are not accustomed to using seat belts on these vehicles due to the current lack of availability of belts in these vehicles and the fact that passengers have not yet been educated regarding the benefits of buckling up in a large bus.

Thus, we estimate that the proposed rule would reduce the number of seriously injured occupants by approximately 4 annually. We estimate that 3.1 equivalent lives are saved annually if 15 percent of occupants use seat belts, and approximately 2.3 equivalent lives are saved annually if 84 percent of occupants use seat belts (see Table 6 below).

enforcement events. The agency has consulted with FMCSA and does not believe that the benefits estimated in this NPRM overlap with the benefits contained in recent FMCSA actions associated with bus safety.

⁷⁶ The PRE prepared in support of today's NPRM assumes that the seat belt use rate on motorcoaches would be between 15 percent, and the percent use in passenger vehicles, which was 84 percent in 2009. In order to maintain consistency with the agency's rule to require seat belts on motorcoaches, we have utilized the same low belt usage rate estimate of 15% from that rule. See Final Regulatory Impact Analysis—FMVSS No. 208. We have also utilized the same source of information to establish the high belt usage rate estimate (the National Occupant Protection Use Survey). Today's NPRM uses the 2009 data which estimates seat belt use of passenger vehicles to be 84%. See 2009 National Occupant Protection Use Survey. More information at: <http://www-nrd.nhtsa.dot.gov/pubs/811100.pdf>.

The agency estimates that, assuming steel is used to comply with the proposed requirements in this rule, material costs for each vehicle will range from \$282 to \$507 and cost between \$0.6 million and \$1.1 million to equip the entire new large bus fleet annually (see Table 7 below). We further estimate that, if steel is used to comply, the total weight increase will range from 564 to 1,114 lb and cost an additional \$2,118 to \$5,523 in fuel per vehicle over the lifetime of the vehicle. The total fuel cost for the new fleet is estimated to be \$4.7 million to \$12.2 million. The total costs would be approximately \$5.3 million to \$13.3 million annually. The cost per equivalent life saved is estimated to be between \$2.09 million and \$6.42 million (see Table 8 below).

All the available information indicates that this proposed rule—if made final—would be cost beneficial. Further, the agency anticipates that the projected net impact on the economy will be closer to the estimates for the 15% belt use rates than the 84% belt use rate. We note that the above estimates for the cost per equivalent life of this rule vary due to uncertainties regarding seat belt use rates and the incremental increase in weight that is necessary to meet today's proposed structural integrity standard. A large portion of the costs of this structural integrity rule is dependent on this incremental increase in weight. While the agency does not have more specific information regarding the likely weight increase to these vehicles, the agency does believe that seat belt usage rates will be closer to 15% rather than 84% because these vehicles are currently not equipped with seat belts and passengers have not yet been educated regarding the advantages of buckling up during travel on these vehicles. Thus, we anticipate that the proposed rule—if made final—would have a net beneficial impact on the economy that is closer to our estimates assuming a 15% belt use rate.

In addition to our expectation that this proposed rule would be cost beneficial, the agency believes that the cost effectiveness of this proposed rule is not very sensitive to changes in belt usage rates because belted passengers will still realize safety benefits as a result of this rule. Many serious injuries that occur in large bus crashes can occur despite a passenger's use of a safety belt. For example, while a belted passenger may not be ejected, he or she can still be struck by the collapsing side wall of the bus. Therefore, even though increasing belt usage rates may mean that more passenger ejections (and fatalities) will be prevented by seat belts (consequently reducing the number of

⁷⁵ As we further discuss in the PRE supporting today's NPRM, we adjusted the target population based on the projected benefits that would be attributable to those rules. Separately, we also considered whether there have been any recent FMCSA actions which might affect the projected target population and we have tentatively concluded that they would not. FMCSA has issued several recent final rules directed at bus and truck safety, including Medical Certificate Requirements as Part of the Commercial Driver's License in 2008, Drivers of Commercial Vehicles: Restricting the Use of Cellular Phones in 2011, Hours of Service in 2011, and National Registry of Certified Medical Examiners in 2012. In addition, FMCSA has had several recent enforcement efforts to improve bus safety, including several nationwide "Strike Force"

prevented ejections attributable to structural changes), the proposed requirements in this NPRM will still be effective in preventing serious injuries

to belted passengers. Thus, we expect that the monetized value of the benefits of this proposed rule is not very sensitive to fluctuations in belt use—

even though the type of benefit will change.⁷⁷

TABLE 6—ESTIMATED ANNUAL BENEFITS
[Undiscounted Equivalent Lives Saved]

15 percent belt usage	3.09
84 percent belt usage	2.31

TABLE 7—ESTIMATED ANNUAL COSTS
[2010 Dollars]

Potential Costs:	
Material Costs Per Vehicle	\$282 to \$507.
Material Costs, Total New Fleet	\$0.6 million to \$1.1 million.
Fuel Costs per Vehicle @3%	\$2,814 to \$5,523.
Fuel Costs per Vehicle @7%	\$2,118 to \$4,156.
Fuel Costs, Total New Fleet	\$4.7 million to \$12.2 million.
Total Annual Cost	\$5.3 million to \$13.3 million.

TABLE 8—COST PER EQUIVALENT LIFE SAVED
[Across 3% and 7% Discount, 2010 Dollars]

15 percent belt usage	\$2.09 million to \$4.72 million.
84 percent belt usage	\$2.91 million to \$6.42 million.

The cost of reinforcing the roof strength and structural integrity of these vehicles to meet the requirements proposed in this standard would be predominantly dependent upon the material and weight increases necessary to reinforce the superstructure. We estimate that the countermeasures may include stronger roof and side walls, shock resistant latches for emergency exits, stronger seat and luggage rack anchorages, and improved window mounting. As mentioned above, these material costs for each vehicle are estimated to be between \$282 and \$507. However, while the agency assumes in these estimates that steel is applied to reinforce the vehicle structure, the agency is aware that other methods of reinforcing the structure (such as the use of high strength steel sections, rigid polyurethane foam filling to reinforce and stabilize thin walled hollow sections, and optimized designs that redistribute the impact loads and enhance the energy absorption capability) may enable a vehicle to withstand greater crash forces without adding as much weight.⁷⁸ Therefore, while our analysis has assumed the use

of steel, the agency is aware that there may be other countermeasures that weigh less—which could result in lower fuel costs (than we have currently estimated) over the lifetime of the vehicle.

The agency also notes that, in addition to the quantifiable benefits mentioned above, there are certain unquantifiable benefits that can arise from today's proposed rule. Our economic analysis of this proposed rule is only able to calculate the benefits that can be realized in addition to the benefits attributable to proposed rules requiring seat belts and electronic stability control systems. In other words, we are only able to estimate the benefits to passengers whose serious and fatal injuries were not prevented by seat belts. When a passenger that would have been fatally injured due to an ejection is estimated as saved by the use of a seat belt that prevents the ejection, we can no longer estimate additional benefits for that particular passenger.

However, we note that while a fatal ejection may be prevented by the use of seat belts, it is possible that poor structural integrity could still contribute towards an injury for this occupant. The

type of injury that can occur to this occupant (fatal ejection prevented by seat belts but still seriously injured by collapsing structure intruding into the survival space) is similar to our earlier discussion regarding the benefits to belted passengers. However, it is important to note that while the agency was able to estimate benefits to belted passengers whose serious injuries and fatalities were not prevented by the seat belts, the agency is unable to estimate what additional (potential) benefits may be realized by those passengers who have already realized benefits because they were no longer fatally injured in an ejection due to seat belt use. As the agency is unaware of any available information that would permit the agency to quantify this benefit, the agency's economic analysis of this proposed rule only estimates the benefits to occupants that would not have been protected by the use of seat belts.

For further information regarding the aforementioned cost and benefit estimates, please reference the PRE that NHTSA has prepared and placed in the Docket.⁷⁹

⁷⁷ For further information, please reference the Preliminary Regulatory Evaluation prepared in support of this NPRM.

⁷⁸ See Lilley, K. and Mani, A., "Roof-Crush Strength Improvement Using Rigid Polyurethane Foam," SAE Technical Paper 960435, 1996. Available at: <http://subscriptions.sae.org/content/960435/>, see also Liang, C. and Le, G. Optimization of bus rollover strength by consideration of the energy absorption ability. International Journal of Automotive Technology. Vol. 11.(2) 173–185. Available at: <http://www.springerlink.com/content/tk824863k66w0228/export-citation/>.

⁷⁹ The PRE discusses issues relating to the potential costs, benefits and other impacts of this regulatory action. The PRE is available in the docket for this NPRM and may be obtained by downloading it or by contacting Docket Management at the address or telephone number provided at the beginning of this document.

We have tentatively decided not to include retrofitting requirements at this time to require that used buses be retrofitted to meet the rollover structural integrity requirements. The service life of a large bus can be 20 years or longer. It may not be structurally viable to retrofit many of the used large buses that are currently in service. Also, it may not be economically feasible for many for-hire operators (many of which are small businesses) to fund the necessary structural changes. Thus, we have not included the costs of retrofitting in our analysis of the costs and benefits of the proposed rule.

IX. Regulatory Analyses

Executive Order 12866, Executive Order 13563, and DOT Regulatory Policies and Procedures

NHTSA has considered the impact of this rulemaking action under Executive Order 12866, Executive Order 13563, and the Department of Transportation's regulatory policies and procedures (44 FR 11034; February 26, 1979). This NPRM is "significant" and was reviewed under the Executive Order. NHTSA has prepared a PRE for this NPRM.

This NPRM proposes to increase roof strength and structural integrity for certain large bus types by establishing requirements for maintaining survival space, seat and overhead luggage rack retention, emergency exit operability, and window mounting strength during a rollover structural integrity test. This NPRM proposes a test procedure which tilts the vehicle on a platform until the vehicle becomes unstable and rolls over onto a level concrete impact surface.

Beyond the benefits attributable to the rule on seat belts for this same group of vehicles and a possible rulemaking on electronic stability control systems, we estimate that requiring new large buses of these types to meet the aforementioned performance criteria would save approximately 3.1 equivalent lives annually if seat belt usage among occupants is 15 percent, and approximately 2.3 equivalent lives annually if seat belt usage is 84 percent. The total cost of making the necessary structural changes, and of lifetime fuel costs, would be approximately \$5.3 million to \$13.3 million annually (for the entire new fleet). The cost per equivalent life saved is estimated to be between \$2.09 million and \$6.42 million. The benefits, costs, and other impacts of this rulemaking are discussed at length in the PRE.

Executive Order 13609: Promoting International Regulatory Cooperation

The policy statement in section 1 of Executive Order 13609 provides, in part:

The regulatory approaches taken by foreign governments may differ from those taken by U.S. regulatory agencies to address similar issues. In some cases, the differences between the regulatory approaches of U.S. agencies and those of their foreign counterparts might not be necessary and might impair the ability of American businesses to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

As mentioned in the body of this preamble, the agency has considered regulatory approaches taken by foreign governments (namely, the European Union in ECE R.66) and decided to base its proposed rule on ECE R.66. In addition to the goal of reducing unnecessary differences in regulatory requirements between the U.S. and its trading partners, the agency has found the ECE R.66 test to be the most suitable test available for ensuring a minimum reasonable level of protection for passengers traveling in buses that are associated with the highest crash risk. While NHTSA has tentatively determined that it is not able to follow (in certain details) the entirety of the ECE R.66 test and requirements, the agency has explained its rationale for its proposed decisions in the relevant sections above.

Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 et seq., as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions). The Small Business Administration's regulations at 13 CFR part 121 define a small business, in part, as a business entity "which operates primarily within the United States." (13 CFR 121.105(a)). No regulatory flexibility analysis is required if the head of an agency certifies that the rule will not have a significant economic impact on a

substantial number of small entities. The SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities.

NHTSA has considered the effects of this rulemaking action under the Regulatory Flexibility Act. According to 13 CFR 121.201, the Small Business Administration's size standards regulations used to define small business concerns, manufacturers of the vehicles covered by this proposed rule would fall under North American Industry Classification System (NAICS) No. 336111, *Automobile Manufacturing*, which has a size standard of 1,000 employees or fewer. NHTSA estimates that there are 26 manufacturers of these types of vehicles in the United States (including manufacturers of motorcoaches, cutaway buses, second-stage motorcoaches, and other types of large buses covered by this proposal). Using the size standard of 1,000 employees or fewer, we estimate that approximately 10 of these 26 manufacturers would be considered a small business.

The agency does not believe that this proposed rule would have a significant economic impact on those small entities. First, the agency estimates that the incremental costs to each vehicle would be \$282 to \$507 per unit to meet the proposed rule. This incremental cost would not constitute a significant impact given that the average cost of the vehicles covered by this proposed rule ranges from \$200,000 to \$400,000. Further, these incremental costs, which are very small compared to the overall cost of the vehicle, can ultimately be passed on to the purchaser and user.

In addition, the agency believes that certifying compliance with the proposed rule would not have a significant impact on the manufacturers. Small manufacturers have various options available that they may use in certifying compliance with the proposed standard. The economic impact of certifying compliance with the standard would not be significant. One option available to small entities is to certify compliance by using modeling and engineering analyses (such as a plastic hinge analysis of portal frames of the vehicle). ECE R.66 itself accounts for and accommodates this compliance option, and this approach has been used for years by European manufacturers in meeting ECE R.66. Thus, there are established practices and protocols that small manufacturers may use to avail

themselves of this basis for certifying compliance with the standard.

We explained in Section VI., *Regulatory Alternatives*, that the aforementioned engineering analysis model would not be appropriate as the agency's method of assessing the compliance of vehicles with a Federal motor vehicle safety standard. However, manufacturers are not required to use NHTSA's test as the basis for their certification. While the agency's test defined in the proposed regulatory test would be an objective test capable of determining which vehicles meet the minimum requirements, manufacturers can use other methods (such as the alternative compliance options in ECE R.66) in certifying the compliance of their own vehicles. Unlike NHTSA, manufacturers certifying compliance of their own vehicles have more detailed information regarding their own vehicles and can use reasonable engineering analyses to determine whether their vehicles will comply with the proposed requirements using alternative testing methods that may not be suitable for incorporation into an FMVSS.

Under the Motor Vehicle Safety Act, a manufacturer can avoid civil penalties associated with a noncompliance if it showed that it exercised due care in certifying its vehicles. A showing of due care can be based on engineering analyses, computer simulations, and the like, and NHTSA will assess the due care upon which the certification is made by evaluating, among other factors, the size of the manufacturer and its resources. We believe that a small manufacturer would be closely familiar with its vehicle design and would be able to utilize modeling and relevant analyses on a vehicle-by-vehicle basis to reasonably predict whether its design will meet the requirements of today's proposed rule.

Second, the small manufacturer could test body sections of the vehicle, as contemplated by ECE R.66, Alternatives 1 and 2. The manufacturer would be able to "section" the vehicle or otherwise obtain a body section representative of the vehicle and of the weakest section of the vehicle. It could base its certification on these tests, without testing a full vehicle.

Third, we note that in the event small manufacturers elect to conduct a test of a full vehicle, there are various methods available to reduce the costs of the test. One such method is by testing a vehicle which is not completely new. As the proposed requirements in today's NPRM pertain to structural integrity, we believe that a manufacturer could test the relevant body design on an old bus

chassis or other underlying structure, and could sufficiently assess and certify the compliance of the vehicle's structural integrity to the proposed standard. Similarly, the agency believes that more costly portions of the vehicle (such as the engine and other portions of the powertrain) could be replaced in a complete vehicle test of a bus with ballast equal to the weight of the absent components. The small manufacturer could base its certification on such testing, which do not involve a destructive test of an actual vehicle.

Fourth, we also note that the product cycle of these vehicles is significantly longer than other vehicle types. With a longer product cycle, we believe that the costs of certification for manufacturers would be further reduced as the costs of conducting compliance testing and the relevant analyses could be spread over a significantly longer period of time.

Finally, we note that the requirements in today's proposed rule may affect the operators of the buses that are the subject of today's NPRM—some of which may be small businesses—but only indirectly as purchasers of these vehicles. As mentioned above, we anticipate that the impact on these businesses will not be significant because (assuming that additional steel is used for compliance) the expected price increase of the vehicles used by these businesses is small (\$282 to \$507 for each vehicle valued between \$200,000 and \$400,000). Further, we anticipate that fuel costs for these businesses will increase between \$2,118 and \$5,523 (in 2009 dollars) per vehicle over its lifetime. These expected increases in costs are small in comparison to the cost of each of these vehicles. In addition, we anticipate that these costs will equally affect all operators and therefore we expect that small operators will be able to pass these costs onto their consumers.

For the aforementioned reasons, I hereby certify that if made final, this proposed rule would not have a significant economic impact on a substantial number of small entities.

With regard to a retrofit requirement applying to a population of on-road vehicles, the agency has tentatively concluded that requiring retrofitting of existing vehicles would be impracticable and therefore has decided not to propose retrofitting requirements in today's NPRM. An estimated 78.8 percent of the 3,137 motorcoach carriers (according to the 2008 Motorcoach Census) in the United States in 2007 (i.e. about 2,470 carriers) have less than 10 motorcoaches in their fleet. Further, these companies have an average of three vehicles and eleven employees.

While the vehicles included in the motorcoach census are not exactly the same as the vehicles covered in today's proposal, we believe the industry's Motorcoach Census offers a reasonable estimate of the proportion of bus carrier companies that would be affected as owners/operators of the buses covered in today's NPRM.

NHTSA tentatively believes that to include retrofit requirements would be a substantial burden on these small carriers. The service life of each of the vehicles covered under today's proposal can be as much as 20 years or longer. Further, it may not be structurally viable for many of these used large buses to be retrofitted. Thus, NHTSA has tentatively decided not to include such requirements in today's proposal that on-road large buses be retrofitted to meet the roof strength requirements of this proposed rule, but requests comments on the issue. The agency is also seeking comment as to whether the proposed emergency exit and side window glazing retention requirements should be applied to used buses.

Executive Order 13132 (Federalism)

NHTSA has examined today's proposed rule pursuant to Executive Order 13132 (64 FR 43255; Aug. 10, 1999) and concluded that no additional consultation with States, local governments, or their representatives is mandated beyond the rulemaking process. The agency has concluded that the rule does not have sufficient federalism implications to warrant consultation with State and local officials or the preparation of a federalism summary impact statement. The rule does not have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

NHTSA rules can have preemptive effect in two ways. First, the National Traffic and Motor Vehicle Safety Act contains an express preemption provision:

When a motor vehicle safety standard is in effect under this chapter, a State or a political subdivision of a State may prescribe or continue in effect a standard applicable to the same aspect of performance of a motor vehicle or motor vehicle equipment only if the standard is identical to the standard prescribed under this chapter. 49 U.S.C. 30103(b)(1). It is this statutory command by Congress that preempts any non-identical State legislative and administrative law address the same aspect of performance.

The express preemption provision described above is subject to a savings clause under which “[c]ompliance with a motor vehicle safety standard prescribed under this chapter does not exempt a person from liability at common law.” 49 U.S.C. 30103(e) Pursuant to this provision, State common law tort causes of action against motor vehicle manufacturers that might otherwise be preempted by the express preemption provision are generally preserved. However, the Supreme Court has recognized the possibility, in some instances, of implied preemption of State common law tort causes of action by virtue of NHTSA’s rules—even if not expressly preempted.

This second way that NHTSA rules can preempt is dependent upon the existence of an actual conflict between an FMVSS and the higher standard that would effectively be imposed on motor vehicle manufacturers if someone obtained a State common law tort judgment against the manufacturer—notwithstanding the manufacturer’s compliance with the NHTSA standard. Because most NHTSA standards established by an FMVSS are minimum standards, a State common law tort cause of action that seeks to impose a higher standard on motor vehicle manufacturers will generally not be preempted. However, if and when such a conflict does exist—for example, when the standard at issue is both a minimum and a maximum standard—the State common law tort cause of action is impliedly preempted. See *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000).

Pursuant to Executive Order 13132, NHTSA has considered whether this proposed rule could or should preempt State common law causes of action. The agency’s ability to announce its conclusion regarding the preemptive effect of one of its rules reduces the likelihood that preemption will be an issue in any subsequent tort litigation.

To this end, the agency has examined the nature (e.g., the language and structure of the regulatory text) and objectives of today’s proposed rule and does not foresee any potential State requirements that might conflict with it. NHTSA does not intend that this proposed rule preempt state tort law that would effectively impose a higher standard on motor vehicle manufacturers than that established by today’s rule. Establishment of a higher standard by means of State tort law would not conflict with the standards proposed in this NPRM. Without any conflict, there could not be any implied

preemption of a State common law tort cause of action.

National Environmental Policy Act

NHTSA has analyzed this NPRM for the purposes of the National Environmental Policy Act. The agency has determined that implementation of this action would not have any significant impact on the quality of the human environment.

Paperwork Reduction Act

Under the procedures established by the Paperwork Reduction Act of 1995, a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. This rulemaking would not establish any new information collection requirements.

National Technology Transfer and Advancement Act

Under the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Pub. L. 104–113), “all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.” Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies, such as the Society of Automotive Engineers (SAE). The NTTAA directs this agency to provide Congress, through OMB, explanations when the agency decides not to use available and applicable voluntary consensus standards.

While the agency is not aware of any voluntary standards that exist regarding rollover structural integrity for the large buses contemplated in today’s proposed rule, the agency has examined the applicable European Union standard (ECE R.66). As discussed extensively above, we have proposed in this NPRM to adopt an ECE R.66-based test, in part, to avoid requiring manufacturers to meet fundamentally different rollover requirements than those required in the European Union. The areas of today’s proposed rule which differ from ECE R.66, and the reasons in support, are extensively discussed in the earlier sections of this preamble.

Executive Order 12988

With respect to the review of the promulgation of a new regulation, section 3(b) of Executive Order 12988,

“Civil Justice Reform” (61 FR 4729, February 7, 1996) requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect; (2) clearly specifies the effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct, while promoting simplification and burden reduction; (4) clearly 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. This document is consistent with that requirement.

Pursuant to this Order, NHTSA notes as follows. The issue of preemption is discussed above in connection with E.O. 13132. NHTSA notes further that there is no requirement that individuals submit a petition for reconsideration or pursue other administrative proceeding before they may file suit in court.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 requires agencies to prepare a written assessment of the costs, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, of more than \$135 million annually (adjusted for inflation to 2009 dollars with base year of 1995). This NPRM would not result in expenditures by State, local or tribal governments, in the aggregate, or by the private sector in excess of \$135 million annually.

Plain Language

Executive Order 12866 and E.O. 13563 require each agency to write all rules in plain language. Application of the principles of plain language includes consideration of the following questions:

- Have we organized the material to suit the public’s needs?
- Are the requirements in the rule clearly stated?
- Does the rule contain technical language or jargon that isn’t clear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand?
- Would more (but shorter) sections be better?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rule easier to understand?

If you have any responses to these questions, please include them in your comments on this proposal.

Regulation Identifier Number (RIN)

The Department of Transportation assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda.

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).

X. Public Participation

How do I prepare and submit comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the docket number of this document in your comments.

Your comments must not be more than 15 pages long. (49 CFR 553.21). We established this limit to encourage you to write your primary comments in a concise fashion. However, you may attach necessary additional documents to your comments. There is no limit on the length of the attachments.

Comments may also be submitted to the Docket electronically by logging onto the Docket Management System Web site at <http://www.regulations.gov>. Follow the online instructions for submitting comments.

Please note that pursuant to the Data Quality Act, in order for substantive data to be relied upon and used by the agency, it must meet the information quality standards set forth in the OMB and DOT Data Quality Act guidelines. Accordingly, we encourage you to consult the guidelines in preparing your comments. OMB's guidelines may be accessed at <http://www.whitehouse.gov/omb/fedreg/reproducible.html>.

How can I be sure that my comments were received?

If you wish Docket Management to notify you upon its receipt of your

comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail.

How do I submit confidential business information?

If you wish to submit any information under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, NHTSA, at the address given above under **FOR FURTHER INFORMATION CONTACT**. In addition, you should submit a copy, from which you have deleted the claimed confidential business information, to the docket at the address given above under **ADDRESSES**. When you send a comment containing information claimed to be confidential business information, you should include a cover letter setting forth the information specified in our confidential business information regulation. (49 CFR part 512.)

Will the agency consider late comments?

We will consider all comments received before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments that the docket receives after that date. If the docket receives a comment too late for us to consider in developing a final rule (assuming that one is issued), we will consider that comment as an informal suggestion for future rulemaking action.

How can I read the comments submitted by other people?

You may read the comments received by the docket at the address given above under **ADDRESSES**. The hours of the docket are indicated above in the same location. You may also see the comments on the Internet. To read the comments on the Internet, go to <http://www.regulations.gov>. Follow the online instructions for accessing the dockets.

Please note that even after the comment closing date, we will continue to file relevant information in the docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically check the Docket for new material. You can arrange with the docket to be notified when others file comments in the docket. See www.regulations.gov for more information.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicles, motor vehicle safety.

Proposed Regulatory Text

In consideration of the foregoing, NHTSA proposes to amend 49 CFR Part 571 as follows:

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

Subpart B—Federal Motor Vehicle Safety Standards

- 1. The authority citation for part 571 continues to read as follows:

Authority: 49 U.S.C. 322, 30111, 30115, 30117, and 30166; delegation of authority at 49 CFR 1.95.

- 2. Section 571.227 is added to read as follows:

§ 571.227 Standard No. 227; Bus Rollover Structural Integrity.

S1. Scope. This standard establishes performance requirements for bus rollover structural integrity.

S2. Purpose. The purpose of this standard is to reduce death and injuries resulting from the structural collapse of the bus body structure, the unintended opening of emergency exits, and the detachment of window glazing, seats, and overhead luggage racks.

S3. Application.

(a) Subject to S3(b), this standard applies to:

- (1) Over-the-road buses, and
- (2) buses that are not over-the-road buses, and that have a GVWR greater than 11,793 kilograms (26,000 pounds).

(b) This standard does not apply to school buses, transit buses, and perimeter-seating buses.

S4. Definitions.

Anchorage means any component involved in transferring loads to the vehicle structure, including, but not limited to, attachment hardware, frames, and vehicle structure itself.

Over-the-road bus means a bus characterized by an elevated passenger deck located over a baggage compartment.

Perimeter-seating bus means a bus with 7 or fewer designated seating positions rearward of the driver's seating position that are forward-facing or can convert to forward-facing without the use of tools and is not an over-the-road bus.

Stop-request system means a vehicle-integrated system for passenger use to signal to a vehicle operator that they are requesting a stop.

Survival space means a three-dimensional space to be preserved in the occupant compartment during the

rollover structural integrity test. The survival space is all points within the following volume of the occupant compartment:

(1) The front boundary of the survival space is a transverse vertical plane 600 mm in front of the forward most point on the centerline of the front surface of the seat back of the forward most seat when the seat is in its forward most position and the seat back is in the manufacturer's nominal design riding position.

(2) The rear boundary of the survival space is the inside surface of the rear wall of the occupant compartment of the vehicle.

(3) The outer boundary of the survival space at any transverse cross section between or at the front and rear boundaries is defined on each side of the vehicle by the following three line segments:

(i) Segment 1 extends vertically from the floor to an end point that is 500 mm above the floor and 150 mm inboard of the side wall.

(ii) Segment 2 starts at the end point of Segment 1. The end point of Segment 2 is 750 mm vertically above and 250 mm horizontally inboard of the end point of Segment 1.

(iii) Segment 3 is a horizontal line that starts at the end point of Segment 2 and ends at the vertical longitudinal center plane of the vehicle.

Survival space template means a structure that represents a vertical transverse cross section of the survival space as shown in Figure 1. The structure is a minimum of 15 mm thick and secured by a rigid support frame that allows attachment to the vehicle floor.

Transit bus means a bus that is equipped with a stop-request system sold for public transportation provided by, or on behalf of, a State or local government and that is not an over-the-road bus.

S5. Requirements. When tested under the conditions and procedures specified in S6, each bus shall meet the following:

S5.1 No part of the vehicle which is outside the survival space shall intrude into the survival space during the movement of the tilting platform or resulting from impact of the vehicle on the impact surface.

S5.2 Each anchorage of all vehicle seats and interior overhead luggage racks and compartments shall not completely separate from its mounting structure during the movement of the tilting platform or resulting from impact of the vehicle on the impact surface.

S5.3 Emergency exits shall not open during the movement of the tilting

platform or resulting from impact of the vehicle on the impact surface.

S5.4 After the vehicle comes to rest on the impact surface, with the vehicle resting on its side, each roof and rear emergency exit of the vehicle provided in accordance with Standard No. 217 (§ 571.217) shall be capable of releasing and opening according to the requirements specified in that standard.

S5.5 After the vehicle comes to rest on the impact surface, with the vehicle resting on its side, window glazing and each surrounding window frame opposite the impacted side of the vehicle shall not allow the passage of a 102 mm diameter sphere when a force of no more than 22 Newtons is applied to the sphere at any vector in a direction from the interior to the exterior of the vehicle.

S6. Test conditions.

S6.1 Tilting platform.

S6.1.1 The tilting platform has a top surface that rests horizontally at its initial position and is of sufficient size to fully contact the bottom of the vehicle's tires.

S6.1.2 The top surface of the tilting platform, at its initial position, is 800 ± 20 millimeters (mm) above the impact surface specified in S6.1.6.

S6.1.3 The axis of rotation of the tilting platform is a maximum of a 100 mm horizontal distance from the edge of the impact surface closest to the platform and a maximum of 100 mm below the horizontal plane at the top surface of the tilting platform as shown in Figure 3.

S6.1.4 The tilting platform is equipped with wheel supports on the top surface as shown in Figure 3. At each vehicle axle, the wheel closest to the platform's axis of rotation is supported. The wheel supports are positioned to make contact with the outboard tire sidewall of the supported wheels with the vehicle positioned as specified in S6.3.1. Each wheel support has the following dimensions:

(a) The height above the top surface of the tilting platform is no greater than two-thirds of the vertical height of the adjacent tire's sidewall.

(b) The width is a minimum of 19 mm.

(c) The length is a minimum of 500 mm.

(d) The top inboard edge has a radius of 10 mm.

S6.1.5 While raising the platform, the tilting platform roll angle, measured at the outside of each wheel farthest from the pivot point, does not differ by more than one degree.

S6.1.6 The impact surface is horizontal, uniform, dry, and smooth concrete. The impact surface covers an

area that is large enough to ensure that the vehicle does not strike beyond the impact surface edges.

S6.2 Vehicle preparation.

S6.2.1 The vehicle's tires are inflated to the manufacturer's recommended tire pressure.

S6.2.2 Survival space templates may be secured to the bus floor anywhere within the survival space.

S6.2.3 If a seat has adjustable anchorages, the seat may be moved forward or rearward to allow the installation of a survival space template. If a seat has fixed anchorages, the seats may be removed to allow the installation of any testing equipment. Ballast of any weight up to the weight of the removed seat and 68 kg per designated seating position may be secured to the bus floor. The ballasts are not placed farther forward than the forward most point of the vehicle seat immediately in front of the removed seat, and the ballasts are not placed farther rearward than the rear most point of the vehicle seat immediately behind the removed seat.

S6.2.4 The fuel tank is filled to its maximum fuel capacity. All other vehicle fluids are at their maximum capacity. Fluids may be substituted if the weight of the original fluid is maintained.

S6.2.5 Ballasting. The vehicle is loaded to any weight up to and including the gross vehicle weight rating (GVWR). Up to 68 kg of ballast is installed at all designated seating positions that are equipped with occupant restraints. The ballast is placed on the top of each seat cushion and attached securely to the seat frame such that it does not break away from the seat from the time the tilting platform begins movement to after the vehicle comes to rest on the impact surface.

S6.3 Rollover structural integrity test procedure. Each vehicle shall meet the requirements of S5 when prepared as specified in S6.2 and tested in accordance with the procedures set forth below.

S6.3.1 Position the vehicle on the tilting platform as illustrated in the examples of Figures 2 and 3 with its longitudinal centerline parallel to the tilt platform's axis of rotation, the right or left side facing the impact surface at NHTSA's option, and with the outboard tire sidewall at the widest axle within 100 mm of the axis of rotation.

S6.3.2 Attach a rigid wheel support to the tilting platform at each axle of the vehicle so that it contacts the outboard tire sidewall of the wheel closest to the impact surface.

S6.3.3 Block the suspension system of the vehicle to be within ± 25 mm of the normal riding attitude as loaded in S6.2.5.

S6.3.4 Apply the vehicle parking brakes.

S6.3.5 Place the vehicle windows, doors, and emergency exits in the fully closed and latched but not locked positions.

S6.3.6 Tilt the vehicle at a rate not to exceed 5 degrees/sec until it starts to rollover on its own.

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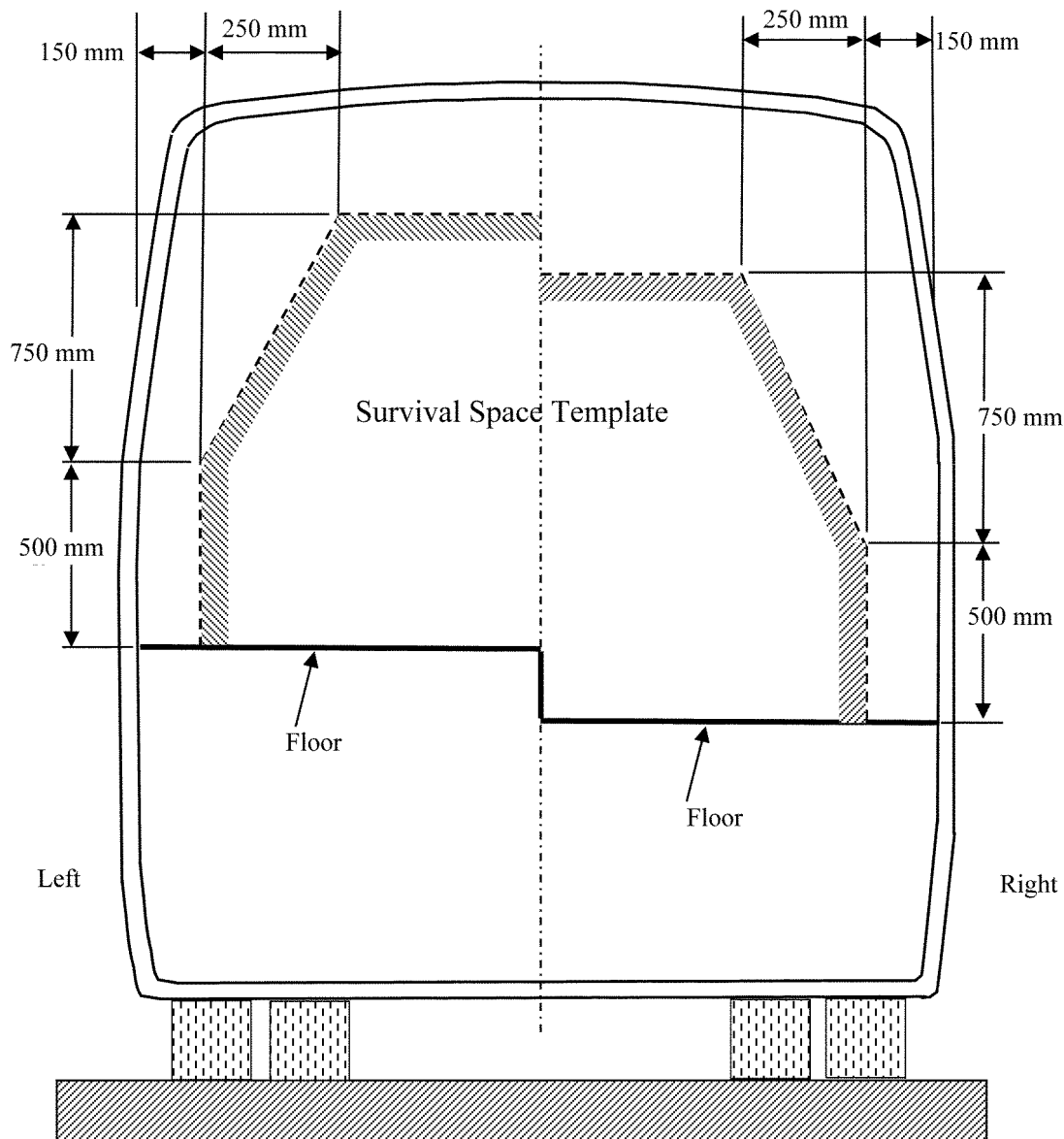


Figure 1: Survival Space Template
(Illustration Purposes)

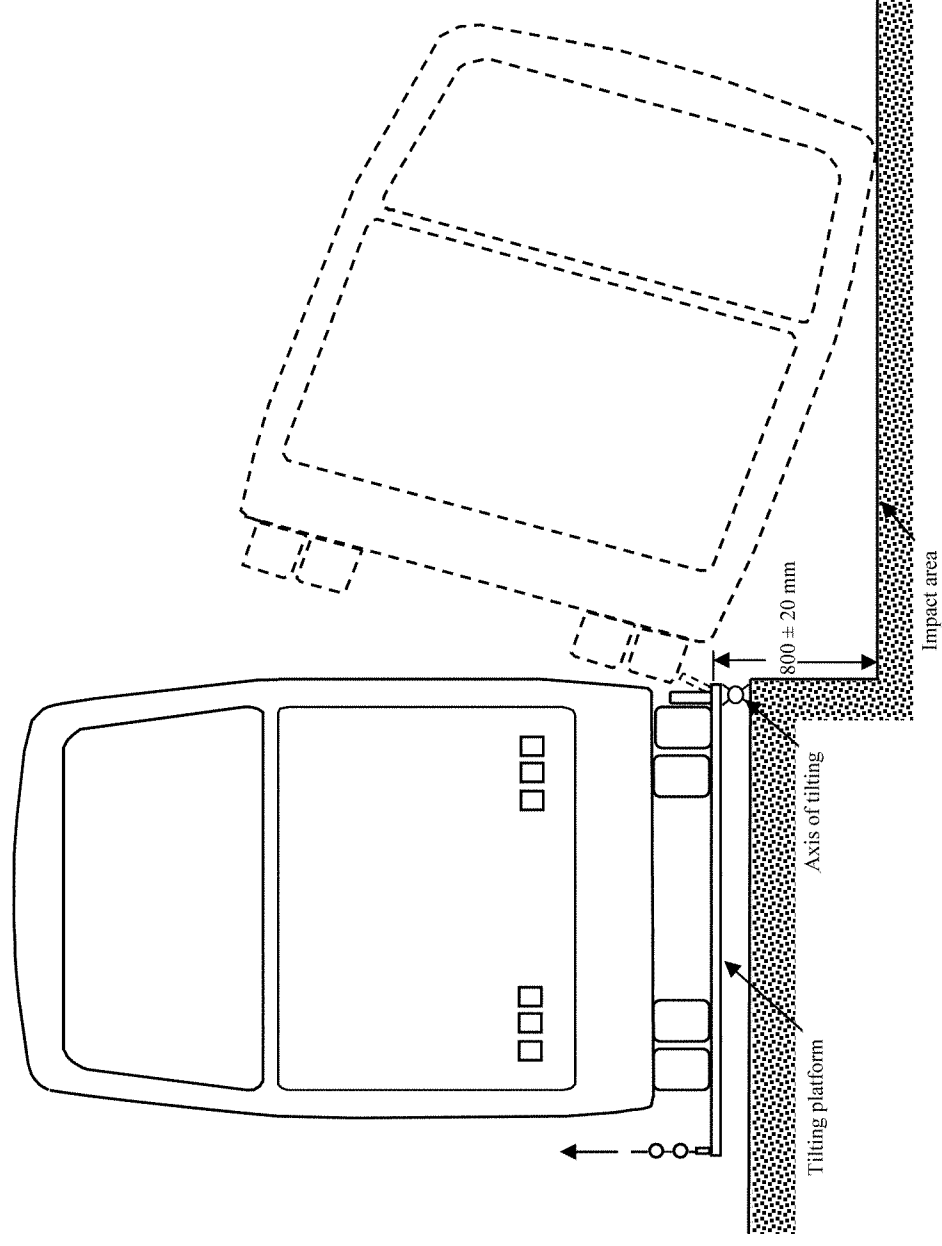


Figure 2: Vehicle on Tilting Platform
(Illustration Purposes)

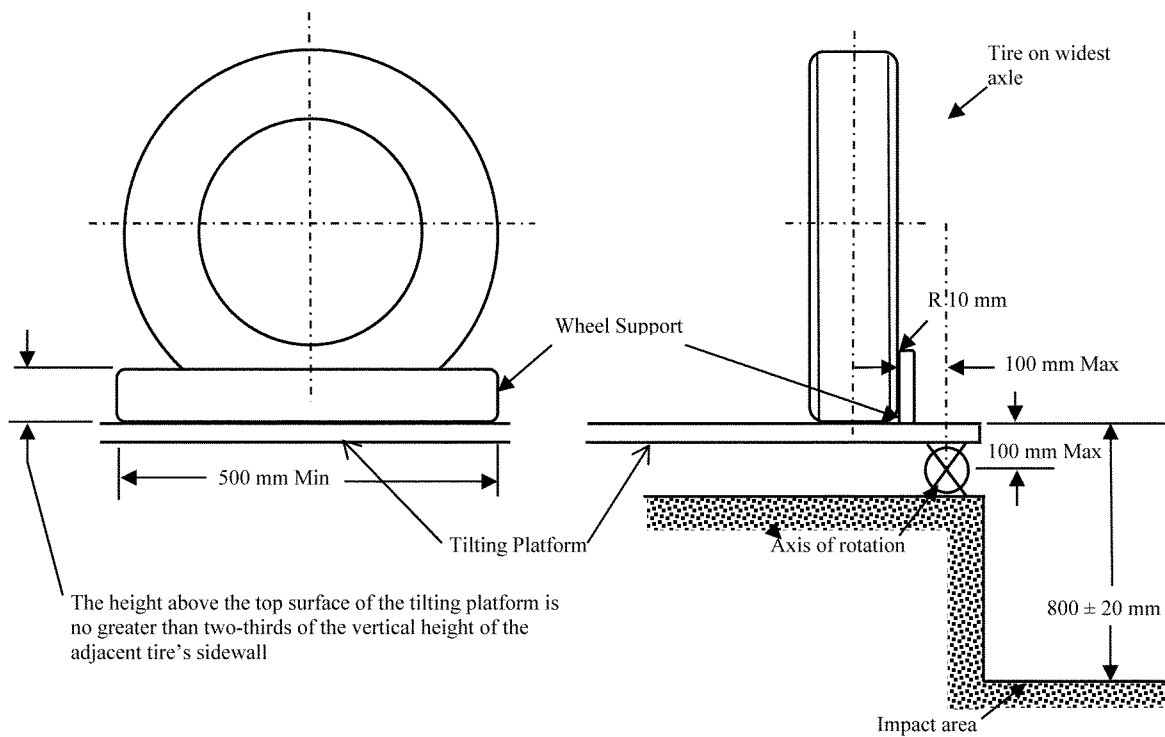


Figure 3: Axis of Rotation
(Illustration Purposes)

Issued in Washington, DC, under authority delegated in 49 CFR 1.95.

David M. Hines,
*Acting Associate Administrator for
Rulemaking.*

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Part VII

Environmental Protection Agency

40 CFR Part 82

Protection of Stratospheric Ozone: Change of Listing Status for Certain
Substitutes Under the Significant New Alternatives Policy Program;
Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA-HQ-OAR-2014-0198; FRL-9910-19-OAR]

RIN 2060-AS18

Protection of Stratospheric Ozone: Change of Listing Status for Certain Substitutes Under the Significant New Alternatives Policy Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: Pursuant to the U.S. Environmental Protection Agency's Significant New Alternatives Policy program, this action proposes to change the status of a number of substitutes that were previously listed as acceptable, based on information showing that other substitutes are available for the same uses that pose lower risk overall to human health and/or the environment. Specifically, this action proposes to modify the listings for certain hydrofluorocarbons in various end-uses in the aerosols, refrigeration and air conditioning, and foam blowing sectors. This action also proposes use conditions that would restrict the use of hydrofluorocarbons to those uses where there are not substitutes available or potentially available that reduce overall risk to human health and/or the environment. This action also proposes to change the status from acceptable to unacceptable for certain hydrochlorofluorocarbons being phased out of production under the Montreal Protocol on Substances that Deplete the Ozone Layer and Section 605(a) of the Clean Air Act.

DATES: Comments must be received on or before October 6, 2014. EPA is planning to hold a public hearing to take place on August 27, 2014, starting at 9 a.m. in Room 1153, EPA East (entrance from 1201 Constitution Avenue), Washington, DC and further information will be provided on EPA's Stratospheric Ozone Web site at www.epa.gov/ozone/snap.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2014-0198, by one of the following methods:

- www.regulations.gov. Follow the on-line instructions for submitting comments.
- Email: A-And-R-Docket@epa.gov.
- Mail: Air and Radiation Docket, Environmental Protection Agency, Mail Code 6102T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, Attention

Docket ID No. EPA-HQ-OAR-2014-0198.

• *Hand Delivery:* EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC, Attention Docket ID No. EPA-HQ-OAR-2014-0198. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-HQ-OAR-2014-0198. 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. For additional instructions on submitting comments, go to Section I.B. of the **SUPPLEMENTARY INFORMATION** section of this document.

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, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the Air and Radiation Docket, EPA/DC, EPA West, Room 3334, 1301

Constitution Ave. NW., Washington, DC. 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 Air and Radiation Docket is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT:

Rebecca von dem Hagen, Stratospheric Protection Division, Office of Atmospheric Programs, Mail Code 6205J, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number (202) 343-9445; fax number (202) 343-2338, email address: vondemhagen.rebecca@epa.gov. Notices and rulemakings under EPA's Significant New Alternatives Policy (SNAP) program are available on EPA's Stratospheric Ozone Web site at www.epa.gov/ozone/snap/regs.

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I. General Information

A. Executive Summary

This notice of proposed rulemaking would change the status of certain substitutes¹ previously found acceptable under the Significant New Alternatives Policy (SNAP) program. EPA is proposing to modify the listings from acceptable to unacceptable for certain hydrofluorocarbons (HFCs) and HFC blends in aerosol, foam blowing, and air conditioning and refrigerant end-uses where other alternatives are available or potentially available that pose overall lower risk. Per the guiding principle stated above, EPA is considering the intersection between the specific HFC or HFC blend and the particular end-use. This action does not propose that any specific HFCs be unacceptable across all sectors and end-uses. EPA is also not proposing that, for any specific sector, the only acceptable substitutes are HFC-free. EPA recognizes that both fluorinated (e.g., HFCs, hydrofluoroolefins (HFOs)) and non-fluorinated (e.g., hydrocarbons (HCs), carbon dioxide (CO₂)) substitutes are potentially acceptable. Instead, consistent with SNAP's history and Clean Air Act (CAA) Section 612, EPA is proposing these modifications based

¹ The terms "substitutes" and "alternatives" are used interchangeably.

on the substitutes being considered, the SNAP criteria for evaluation, and the current suite of other available and potentially available substitutes.

EPA is proposing to modify the following listings by end-use:

(1) For aerosol propellants, we are proposing to list, as of January 1, 2016

- HFC-125 as unacceptable;
- HFC-134a as acceptable, subject to

use conditions, allowing its use only in specific types of technical and medical aerosols (e.g. metered dose inhalers) (and prohibiting its use in consumer aerosols); and

- HFC-227ea as acceptable, subject to use conditions, allowing its use only in metered dose inhalers.

(2) For motor vehicle air conditioning systems in newly manufactured light-duty vehicles, we are proposing to list

- HFC-134a as unacceptable starting with model year (MY) 2021; and

• The refrigerant blends SP34E, R-426A (also known as RS-24), R-416A (also known as HCFC Blend Beta or FRIGC FR12), R-406A, R-414A (also known as HCFC Blend Xi or GHG-X4), R-414B (also known as HCFC Blend Omicron), HCFC Blend Delta (also known as Free Zone), Freeze 12, GHG-X5, and HCFC Blend Lambda (also known as GHG-HP) as unacceptable starting with MY 2017.

(3) For new and retrofit retail food refrigeration (including stand-alone equipment, condensing units, direct supermarket systems, and indirect supermarket systems) and new and retrofit vending machines, we are proposing to list, as of January 1, 2016

- The HFC blends R-507A and R-404A as unacceptable.

(4) For new and retrofit retail food refrigeration (including direct supermarket systems and indirect supermarket systems), we are proposing to list, as of January 1, 2016

- HFC-227ea, R-407B, R-421B, R-422A, R-422C, R-422D, R-428A, and R-434A as unacceptable.

(5) For new stand-alone retail food refrigeration and new vending machines, we are proposing to list, as of January 1, 2016

- HFC-134a and certain other HFC refrigerant blends as unacceptable.

(6) For foam blowing agents, we are proposing to list, as of January 1, 2017, except where allowed under a narrowed use limit,

- HFC-134a and blends thereof as unacceptable in all foam blowing end-uses;

• HFC-143a, HFC-245fa and HFC-365mfc and blends thereof, and the HFC blends Formacel B, and Formacel Z-6 as unacceptable in all foam blowing end-uses where they are currently listed as

acceptable, except for spray foam applications; and

- The HFC blend Formacel TI as unacceptable in all foam blowing end-uses where it is currently listed as acceptable.

In general, EPA is proposing modifications to the listings based on the SNAP program's comparative risk framework. The sections that follow provide the analyses supporting the proposed listing modifications and the dates when the modified listings would apply to users of these substitutes. In addition, EPA has prepared supporting documentation on this rule including market characterizations, analyses of

costs associated with sector transitions, estimated benefits associated with the transition to alternatives, and potential small business impacts.^{2 3 4 5 6 7 8} The emissions reductions from this proposed rule are estimated to be 31 to 42 million metric tons of carbon dioxide equivalent (MMTCO₂e) in 2020. These documents are available in the docket for commenters to review. EPA is planning to prepare a consolidated analysis document.

EPA is also proposing to modify the listings for hydrochlorofluorocarbon (HCFC)—141b, HCFC—142b, and HCFC—22, as well as blends that contain these

substances, from acceptable to unacceptable in aerosols, foam blowing agents, fire suppression and explosion protection agents, sterilants, and adhesives, coatings and inks. These modifications reflect the existing regulations promulgated under CAA sections 605(a) and 610(d) codified at 40 CFR part 82 subparts A and C. The modified listings would take effect 60 days following issuance of a final rule promulgating this proposal.

B. Does this action apply to me?

Potential entities that may be affected by this proposed rule include:

TABLE 1—POTENTIALLY REGULATED ENTITIES BY NORTH AMERICAN INDUSTRIAL CLASSIFICATION SYSTEM (NAICS) CODE

Category	NAICS Code	Description of regulated entities
Industry	238220	Plumbing, Heating, and Air Conditioning Contractors
Industry	324191	Petroleum Lubricating Oil and Grease Manufacturing
Industry	325199	All Other Basic Organic Chemical Manufacturing
Industry	325412	Pharmaceutical Preparation Manufacturing
Industry	325510	Paint and Coating Manufacturing
Industry	325520	Adhesive Manufacturing
Industry	325612	Polishes and Other Sanitation Goods
Industry	325620	Toilet Preparation Manufacturing
Industry	325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing
Industry	326140	Polystyrene Foam Product Manufacturing
Industry	326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing
Industry	333415	Air Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing
Industry	336211	Motor Vehicle Body Manufacturing
Industry	3363	Motor Vehicle Parts Manufacturing
Industry	339113	Surgical Appliance and Supplies Manufacturing
Retail	423620	Household Appliances, Electric Housewares, and Consumer Electronics Merchant Wholesalers
Retail	423740	Refrigeration Equipment and Supplies Merchant Wholesalers
Retail	44511	Supermarkets and Other Grocery (except Convenience) Stores
Retail	445110	Supermarkets and Other Grocery (except Convenience) Stores
Retail	445120	Convenience Stores
Retail	44521	Meat Markets
Retail	44522	Fish and Seafood Markets
Retail	44523	Fruit and Vegetable Markets
Retail	445291	Baked Goods Stores
Retail	445292	Confectionary and Nut Stores
Retail	445299	All Other Specialty Food Stores
Retail	4453	Beer, Wine, and Liquor Stores
Retail	446110	Pharmacies and Drug Stores
Retail	44711	Gasoline Stations with Convenience Stores
Retail	452910	Warehouse Clubs and Supercenters
Retail	452990	All Other General Merchandise Stores
Services	72111	Hotels (except Casino Hotels) and Motels
Services	72112	Casino Hotels
Retail	72241	Drinking Places (Alcoholic Beverages)
Retail	722513	Limited-Service Restaurants
Retail	722514	Cafeterias, Grill Buffets, and Buffets
Retail	722515	Snack and Nonalcoholic Beverage Bars

This table is not intended to be exhaustive, but rather a guide regarding

entities likely to use the substitute whose use is regulated by this action. If

you have any questions about whether this action applies to a particular entity,

² ICF, 2014a. Market Characterization of the U.S. Aerosols Industry. Prepared for the U.S. Environmental Protection Agency. May, 2014.

³ ICF, 2014b. Market Characterization of the U.S. Foams Industry. Prepared for the U.S. Environmental Protection Agency. May, 2014.

⁴ ICF, 2014c. Market Characterization of the U.S. Commercial Refrigeration Industry. Prepared for the U.S. Environmental Protection Agency. May, 2014.

⁵ ICF, 2014d. Market Characterization of the Motor Vehicle Air Conditioning Industry. Prepared for the U.S. Environmental Protection Agency. May, 2014.

⁶ ICF, 2014f. Economic Impact Screening Analysis for Regulatory Options to Change Listing Status of High-GWP Alternatives. April, 2014.

⁷ EPA, 2014. Climate Benefits of the SNAP Program Status Change Rule, June 2014.

⁸ ICF, 2014g. Revised Preliminary Cost Analysis for Regulatory Options to Change Listing Status of High-GWP Alternatives. June 2014.

consult the person listed in the above section, **FOR FURTHER INFORMATION CONTACT.**

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

1. Submitting Confidential Business Information (CBI)

Do not submit confidential information to EPA through www.regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for Preparing Your Comments

When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date, and page number).
- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a CFR part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline.

D. What acronyms and abbreviations are used in the preamble?

Below is a list of acronyms and abbreviations used in the preamble of this document:

ACGIH—American Conference of Governmental Industrial Hygienists
 AIHA—American Industrial Hygiene Association

CAA—Clean Air Act
 CAS Reg. No.—Chemical Abstracts Service Registry Identification Number
 CBI—Confidential Business Information
 CFC—Chlorofluorocarbon
 CFR—Code of Federal Regulations
 CH₄—Methane
 CO₂—Carbon dioxide
 CO₂eq—Carbon dioxide equivalent
 DOE—United States Department of Energy
 EIA—Environmental Investigation Agency-US
 EO—Executive Order
 EPA—United States Environmental Protection Agency
 EU—European Union
 FDA—United States Food and Drug Administration
 FR—**Federal Register**
 GHG—Greenhouse gas
 Gt—Gigaton
 GWP—Global warming potential
 HC—Hydrocarbon
 HCFC—Hydrochlorofluorocarbon
 HFC—Hydrofluorocarbon
 HFO—Hydrofluoroolefin
 ICF—ICF International, Inc.
 ICR—Information collection request
 IGSD—Institute for Governance and Sustainable Development
 IPCC—Intergovernmental Panel on Climate Change
 MDI—metered dose inhaler
 MVAC—Motor vehicle air conditioning
 N₂—Nitrogen
 NAICS—North American Industrial Classification System
 NIOSH—United States National Institute for Occupational Safety and Health
 NRDC—Natural Resources Defense Council
 NTTAA—National Technology Transfer and Advancement Act
 OEM—Original equipment manufacturer
 ODP—Ozone depletion potential
 ODS—Ozone-depleting substance
 OMB—United States Office of Management and Budget
 OSHA—United States Occupational Safety and Health Administration
 PEL—Permissible exposure limit
 PFC—Perfluorocarbons
 ppm—Parts per million
 PRA—Paperwork Reduction Act
 REL—Recommended exposure limit
 RFA—Regulatory Flexibility Act
 SF₆—Sulfur hexafluoride
 SNAP—Significant New Alternatives Policy
 SRES—Special Report on Emissions Scenarios
 TLV—Threshold limit value
 TWA—Time-weighted average
 UMRA—Unfunded Mandates Reform Act
 VOC—Volatile organic compounds
 WEEL—Workplace Environmental Exposure Limit

II. How does the SNAP program work?

A. What are the statutory requirements and authority for the SNAP program?

Section 612 of the Clean Air Act (CAA) requires the U.S. Environmental Protection Agency (hereafter referred to as EPA or the Agency) to develop a program for evaluating alternatives to

ozone-depleting substances. This program is known as the Significant New Alternatives Policy (SNAP) program. The major provisions of section 612 are:

1. Rulemaking

Section 612(c) requires EPA to promulgate rules making it unlawful to replace any class I (e.g., chlorofluorocarbon, halon, carbon tetrachloride, methyl chloroform, methyl bromide, and hydrobromofluorocarbon) or class II (e.g., hydrochlorofluorocarbon) substance with any substitute that the Administrator determines may present adverse effects to human health or the environment where the Administrator has identified an alternative that (1) reduces the overall risk to human health and the environment and (2) is currently or potentially available.

2. Listing of Unacceptable/Acceptable Substitutes

Section 612(c) requires EPA to publish a list of the substitutes that it finds to be unacceptable for specific uses and to publish a corresponding list of acceptable alternatives for specific uses. The list of “acceptable” substitutes is found at www.epa.gov/ozone/snap/lists and the lists of “unacceptable,” “acceptable subject to use conditions,” and “acceptable subject to narrowed use limits” substitutes are found in the appendices to 40 CFR part 82 subpart G.

3. Petition Process

Section 612(d) grants the right to any person to petition EPA to add a substance to, or delete a substance from, the lists published in accordance with section 612(c). The Agency has 90 days to grant or deny a petition. Where the Agency grants the petition, EPA must publish the revised lists within an additional six months.

4. 90-day Notification

Section 612(e) directs EPA to require any person who produces a chemical substitute for a class I substance to notify the Agency not less than 90 days before new or existing chemicals are introduced into interstate commerce for significant new uses as substitutes for a class I substance. The producer must also provide the Agency with the producer's unpublished health and safety studies on such substitutes.

5. Outreach

Section 612(b)(1) states that the Administrator shall seek to maximize the use of federal research facilities and resources to assist users of class I and II substances in identifying and

developing alternatives to the use of such substances in key commercial applications.

6. Clearinghouse

Section 612(b)(4) requires the Agency to set up a public clearinghouse of alternative chemicals, product substitutes, and alternative manufacturing processes that are available for products and manufacturing processes which use class I and II substances.

B. What are EPA's regulations implementing CAA section 612?

On March 18, 1994, EPA published the original rulemaking (59 FR 13044) which established the process for administering the SNAP program and issued EPA's first lists identifying acceptable and unacceptable substitutes in major industrial use sectors (40 CFR part 82, subpart G). These sectors are the following: Refrigeration and air conditioning; foam blowing; solvents cleaning; fire suppression and explosion protection; sterilants; aerosols; adhesives, coatings and inks; and tobacco expansion. These sectors comprise the principal industrial sectors that historically consumed the largest volumes of ozone-depleting substances (ODS).

C. How do the regulations for the SNAP program work?

Under the SNAP regulations, anyone who produces a substitute to replace a class I or II ODS in one of the eight major industrial use sectors must provide the Agency with notice and the required health and safety information on the substitute at least 90 days before introducing it into interstate commerce for significant new use as an alternative. 40 CFR 82.176(a). While this requirement typically applies to chemical manufacturers as the person likely to be planning to introduce the substitute into interstate commerce,⁹ it may also apply to importers, formulators, equipment manufacturers, or end-users¹⁰ when they are

responsible for introducing a substitute into commerce. The 90-day SNAP review process begins once EPA receives the submission and determines that the submission includes complete and adequate data. 40 CFR 82.180(a). The CAA and the SNAP regulations, 40 CFR 82.174(a), prohibit use of a substitute earlier than 90 days after a complete submission has been provided to the Agency.

The Agency has identified four possible decision categories for substitute submissions: Acceptable; acceptable subject to use conditions; acceptable subject to narrowed use limits; and unacceptable.¹¹ 40 CFR 82.180(b). Use conditions and narrowed use limits are both considered "use restrictions" and are explained below. Substitutes that are deemed acceptable without use conditions can be used for all applications within the relevant end-uses within the sector and without limits under SNAP on how they may be used. Substitutes that are acceptable subject to use restrictions may be used only in accordance with those restrictions. Substitutes that are found to be unacceptable may not be used after the date specified in the rulemaking adding such substitute to the list of unacceptable substitutes.¹²

After reviewing a substitute, the Agency may determine that a substitute is acceptable only if certain conditions in the way that the substitute is used are met to ensure risks to human health and the environment are not significantly greater than other available substitutes. EPA describes such substitutes as "acceptable subject to use conditions." Entities that use these substitutes without meeting the associated use conditions are in violation of section 612 of the Clean Air Act and EPA's SNAP regulations. 40 CFR 82.174(c).

For some substitutes, the Agency may permit a narrow range of use within an end-use or sector. For example, the Agency may limit the use of a substitute to certain end-uses or specific applications within an industry sector. The Agency requires a user of a

narrowed use substitute to demonstrate that no other acceptable substitutes are available for their specific application. EPA describes these substitutes as "acceptable subject to narrowed use limits." A person using a substitute that is acceptable subject to narrowed use limits in applications and end-uses that are not consistent with the narrowed use limit is using these substitutes in violation of section 612 of the CAA and EPA's SNAP regulations. 40 CFR 82.174(c).

The section 612 mandate for EPA to prohibit the use of a substitute that may present risk to human health or the environment where a lower risk alternative is available or potentially available¹³ provides EPA with the authority to change the listing status of a particular substitute if such a change is justified by new information or changed circumstance.

The Agency publishes its SNAP program decisions in the **Federal Register**. EPA uses notice-and-comment rulemaking to place any alternative on the list of prohibited substitutes, to list a substitute as acceptable only subject to use conditions or narrowed use limits, or to remove a substitute from either the list of prohibited or acceptable substitutes.

In contrast, EPA publishes "notices of acceptability" to notify the public of substitutes that are deemed acceptable with no restrictions. As described in the preamble to the rule initially implementing the SNAP program (59 FR 13044; March 18, 1994), EPA does not believe that rulemaking procedures are necessary to list substitutes that are acceptable without restrictions because such listings neither impose any sanction nor prevent anyone from using a substitute.

Many SNAP listings include "comments" or "further information" to provide additional information on substitutes. Since this additional information is not part of the regulatory decision, these statements are not binding for use of the substitute under the SNAP program. However, regulatory requirements so listed are binding under other regulatory programs (e.g., worker protection regulations promulgated by the U.S. Occupational Safety and Health

⁹ As defined at 40 CFR 82.104 "interstate commerce" means the distribution or transportation of any product between one state, territory, possession or the District of Columbia, and another state, territory, possession or the District of Columbia, or the sale, use or manufacture of any product in more than one state, territory, possession or District of Columbia. The entry points for which a product is introduced into interstate commerce are the release of a product from the facility in which the product was manufactured, the entry into a warehouse from which the domestic manufacturer releases the product for sale or distribution, and at the site of United States Customs clearance.

¹⁰ As defined at 40 CFR 82.172 "end-use" means processes or classes of specific applications within major industrial sectors where a substitute is used to replace an ozone-depleting substance.

¹¹ The SNAP regulations also include "pending," referring to submissions for which EPA has not reached a determination, under this provision.

¹² As defined at 40 CFR 82.172, "use" means any use of a substitute for a Class I or Class II ozone-depleting compound, including but not limited to use in a manufacturing process or product, in consumption by the end-user, or in intermediate uses, such as formulation or packaging for other subsequent uses. This definition of use encompasses manufacturing process of products both for domestic use and for export. Substitutes manufactured within the United States exclusively for export are subject to SNAP requirements since the definition of use in the rule includes use in the manufacturing process, which occurs within the United States.

¹³ In addition to acceptable commercially available substitutes, the SNAP program may consider potentially available substitutes. The SNAP program's definition of "potentially available" is "any alternative for which adequate health, safety, and environmental data, as required for the SNAP notification process, exist to make a determination of acceptability, and which the Agency reasonably believes to be technically feasible, even if not all testing has yet been completed and the alternative is not yet produced or sold." (40 CFR 82.172)

Administration (OSHA)). The “further information” classification does not necessarily include all other legal obligations pertaining to the use of the substitute. While the items listed are not legally binding under the SNAP program, EPA encourages users of substitutes to apply all statements in the “further information” column in their use of these substitutes. In many instances, the information simply refers to sound operating practices that have already been identified in existing industry and/or building codes or standards. Thus, many of the statements, if adopted, would not require the affected user to make significant changes in existing operating practices.

D. What are the guiding principles of the SNAP program?

The seven guiding principles of the SNAP program, elaborated in the preamble to the initial SNAP rule and based on section 612, are discussed below.

- *Evaluate substitutes within a comparative risk framework*

The SNAP program evaluates the risk of alternative compounds compared to available or potentially available substitutes to the ozone depleting compounds which they are intended to replace. The risk factors that are considered include ozone depletion potential as well as flammability, toxicity, occupational health and safety, and contributions to climate change and other environmental factors.

- *Do not require that substitutes be risk free to be found acceptable*

For substitutes to be found acceptable they must pose less risk than other substitutes, but they do not have to be risk free. Where risks of a substitute would otherwise be higher than other substitutes, EPA may find these alternatives acceptable subject to use conditions or narrowed use limits that would manage the risk.

- *Restrict those substitutes that are significantly worse*

EPA does not intend to restrict a substitute if it has only marginally greater risk. Drawing fine distinctions would be extremely difficult. The Agency also does not want to intercede in the market's choice of substitutes by listing as unacceptable all but a few substitutes for each end-use. Thus, the Agency will not list a potential substitute as unacceptable unless EPA determines that the substitute is significantly more harmful to human health or the environment than other available or potentially available alternatives.

- *Evaluate risks by use*

Central to SNAP's evaluations is the intersection between the characteristics of the substitute itself and its specific end-use application. Section 612 requires that substitutes be evaluated by use. Environmental and human health exposures can vary significantly depending on the particular application of a substitute. Thus, the risk characterizations must be designed to represent differences in the environmental and human health effects associated with diverse uses. This approach cannot, however, imply fundamental tradeoffs with respect to different types of risk to either the environment or to human health.

- *Provide the regulated community with information as soon as possible*

The Agency recognizes the need to provide the regulated community with information on the acceptability of various substitutes as soon as possible. To do so, EPA issues notices or determinations of acceptability and rules identifying substitutes as unacceptable, acceptable to use conditions or acceptable subject to narrowed use limits in the **Federal Register**. In addition, we maintain lists of acceptable and unacceptable alternatives on our Web site, www.epa.gov/ozone/snap.

- *Do not endorse products manufactured by specific companies*

The Agency does not issue company-specific product endorsements. In many cases, the Agency may base its analysis on data received on individual products, but the addition of a substitute to the acceptable list based on that analysis does not represent an endorsement of that company's products.

- *Defer to other environmental regulations when warranted*

In some cases, EPA and other federal agencies have developed extensive regulations under other sections of the CAA or other statutes that address any potential environmental impacts that may result from the use of alternatives to class I and class II substances. For example, use of some substitutes may in some cases entail increased use of chemicals that contribute to tropospheric air pollution. The SNAP program takes existing regulations under other programs into account when reviewing substitutes.

E. What are EPA's criteria for evaluating substitutes under the SNAP program?

EPA applies the same criteria for determining whether a substitute is acceptable or unacceptable. These criteria, which can be found at § 82.180(a)(7), include atmospheric effects and related health and

environmental impacts, ecosystem risks, consumer risks, flammability, and cost and availability of the substitute. To enable EPA to assess these criteria, we require submitters to include various information including ozone depletion potential (ODP), global warming potential (GWP), toxicity, flammability, and the potential for human exposure.

When evaluating potential substitutes, EPA evaluates these criteria in the following groupings:

- *Atmospheric effects*—The SNAP program evaluates the potential contributions to both ozone depletion and climate change. The SNAP program considers the ozone depletion potential and the 100-year integrated GWP of compounds to assess atmospheric effects.

- *Exposure assessments*—The SNAP program uses exposure assessments to estimate concentration levels of substitutes to which workers, consumers, the general population, and environmental receptors may be exposed over a determined period of time. These assessments are based on personal monitoring data or area sampling data if available. Exposure assessments may be conducted for many types of releases including:

- (1) Releases in the workplace and in homes;
- (2) Releases to ambient air and surface water;
- (3) Releases from the management of solid wastes.

- *Toxicity data*—The SNAP program uses toxicity data to assess the possible health and environmental effects of exposure to substitutes. We use broad health-based criteria such as:

- (1) Permissible Exposure Limits (PELs) for occupational exposure;
- (2) Inhalation reference concentrations (RfCs) for non-carcinogenic effects on the general population;
- (3) Cancer slope factors for carcinogenic risk to members of the general population.

When considering risks in the workplace, if OSHA has not issued a PEL for a compound, EPA then considers Recommended Exposure Limits from the National Institute for Occupational Safety and Health, Workplace Environmental Exposure Limits (WEELs) set by the American Industrial Hygiene Association, or Threshold Limit Values set by the American Conference of Governmental Industrial Hygienists. If limits for occupational exposure or exposure to the general population are not already established, then EPA derives these values following the Agency's peer reviewed guidelines. Exposure

information is combined with toxicity information to explore any basis for concern. Toxicity data are used with existing EPA guidelines to develop health-based limits for interim use in these risk characterizations.

- **Flammability**—The SNAP program examines flammability as a safety concern for workers and consumers. EPA assesses flammability risk using data on:

- (1) Flash point and flammability limits (e.g. OSHA flammability/ combustibility classifications);

- (2) Data on testing of blends with flammable components;

- (3) Test data on flammability in consumer applications conducted by independent laboratories; and

- (4) Information on flammability risk mitigation techniques.

- **Other environmental impacts**—The SNAP program also examines other potential environmental impacts such as ecotoxicity and local air quality impacts. A compound that is likely to be discharged to water may be evaluated for impacts on aquatic life. Some substitutes are volatile organic compounds (VOCs). EPA also notes whenever a potential substitute is considered a hazardous or toxic air pollutant (under CAA sections 112 (b) and 202 (l)) or hazardous waste under the Resource Conservation and Recovery Act subtitle C regulations.

Over the past twenty years, the menu of substitutes has become much broader and a great deal of new information has been developed on many substitutes. Because the overall goal of the SNAP program is to ensure that substitutes listed as acceptable do not pose significantly greater risk to human health and the environment than other available substitutes, the SNAP criteria should be informed by our current overall understanding of environmental and human health impacts and our experience with and current knowledge about available and potentially available substitutes. Over time, the range of substitutes reviewed by SNAP has changed, and, at the same time, scientific approaches have evolved to more accurately assess the potential environmental and human health impacts of these chemicals and alternative technologies.

F. How are SNAP determinations updated?

Three mechanisms exist for modifying the list of SNAP determinations. First, under section 612(d), the Agency must review and either grant or deny petitions to add or delete substances from the SNAP list of acceptable or unacceptable substitutes. That provision

allows any person to petition the Administrator to add a substance to the list of acceptable or unacceptable substitutes or to remove a substance from either list. The second means is through the notifications which must be submitted to EPA 90 days before introduction of a substitute into interstate commerce for significant new use as an alternative to a class I or class II substance. These 90-day notifications are required by section 612(e) of the CAA for producers of substitutes to class I substances for new uses and, in all other cases, by EPA regulations issued under sections 114 and 301 of the Act to implement section 612(c).

Finally, we interpret the section 612 mandate to find substitutes acceptable or unacceptable to include the authority to act on our own to add or remove a substance from the SNAP lists. In determining whether to add or remove a substance from the SNAP lists, we consider whether there are other available substitutes that pose a lower risk to human health and the environment. In determining whether to modify a listing of a substitute we consider new data not considered at the time of our original listing decision, including information on new substitutes and new information on substitutes previously reviewed.

G. What does EPA consider in deciding whether to modify a determination?

As described in this document and elsewhere, including in the original SNAP rulemaking published in the **Federal Register** on March 18, 1994 (59 FR 13044), section 612 of the CAA requires EPA to list as unacceptable any substitute substance where it finds that there are other substitutes currently or potentially available that reduce overall risk to human health and the environment. In addition to comparing the human health and environmental effects of other available or potentially available substitutes for the same end-uses, we also compare substitutes to the ozone-depleting substances being phased out under the *Montreal Protocol on Substances that Deplete the Ozone Layer* (Montreal Protocol) and under the CAA.

The original SNAP rule included submission requirements and presented the environmental and health risk factors that the SNAP program considers in its comparative risk framework. Environmental and human health exposures can vary significantly depending on the particular application of a substitute; therefore, EPA makes decisions based on the particular end-use where a substitute is to be used. EPA has, in many cases, found certain

substitutes acceptable only for limited end-uses or subject to use restrictions.

In May 2013 EPA stated:

EPA recognizes that during the nearly two-decade long history of the SNAP program, new alternatives and new information about alternatives have emerged. To the extent possible, EPA considers new information and improved understanding of the risk factors for the environment and human health in the context of the available or potentially available alternatives for a given use. (78 FR 29035)

It has now been about twenty years since the initial SNAP rule was promulgated. In that period, the menu of available alternatives has expanded greatly and now includes many substitutes with diverse characteristics and effects on human health and the environment. When the SNAP program began, the number of substitutes available for consideration was, for many end-uses, somewhat limited. While the SNAP program's initial comparative assessments of overall risk to human health and the environment were rigorous, often there were few substitutes to apply the comparative assessment. The immediacy of the class I phaseout often meant that SNAP listed class II ODS (i.e., HCFCs) as acceptable, recognizing that they too would be phased out and were only an interim solution. Other Title VI provisions such as the section 610 Nonessential Products Ban and the section 605 Use Restriction meant a listing under the SNAP program did not convey permanence.

Since EPA issued the initial SNAP rule in 1994, the Agency has issued 18 rules and 28 notices expanding the menu of options for all SNAP sectors and end-uses. Comparisons today are to a broader range of options—both chemical and non-chemical—than at the inception of the SNAP program. Industry experience with these substitutes has also grown during the history of the program. This varies by sector and by end-use.

In addition to an expanding menu of substitutes, developments over the past 20 years have improved our understanding of global environmental issues. With regards to that information, many of the substitute-specific actions proposed in this rule have undergone comparative assessments that consider our evolving understanding of climate change. GWPs and climate effects are not new elements in our evaluation framework, but along with all of our review criteria the amount and quality of information has expanded.

To the extent possible, EPA's ongoing management of the SNAP program considers new information and

improved understanding of the risk to the environment and human health. EPA previously has taken several actions revising listing determinations from acceptable or acceptable with use conditions to unacceptable based on information made available to EPA after a listing was issued. For example, on January 26, 1999, EPA listed the refrigerant known by the trade name MT-31 as unacceptable for all refrigeration and air conditioning end-uses. EPA previously listed this blend as an acceptable substitute in various end-uses within the refrigeration and air conditioning sector (June 3, 1997; 62 FR 30275). Based on new information about the toxicity of one of the chemicals in the blend, EPA subsequently removed MT-31 from the list of acceptable substitutes and listed it as unacceptable in all refrigeration and air conditioning end-uses (January 26, 1999; 64 FR 3861).

Another example of EPA revising a listing determination occurred in 2007 when EPA listed HCFC-22 and HCFC-142b as unacceptable for use in the foam sector (March 28, 2007; 72 FR 14432). These HCFCs, which are ozone depleting and subject to a global production phaseout, were initially listed as acceptable substitutes since they had a lower ODP than the substances they were replacing and there were no other available substitutes that posed lower risk at the time of EPA's listing decision. HCFCs offered a path forward for some sectors and end-uses at a time when substitutes were far more limited. In light of the expanded availability of alternative substitutes with lower overall risk to human health and the environment in specific foam end-uses, and taking into account the 2010 class II ODS phasedown step, EPA changed the listing for these HCFCs in these end-uses from acceptable to unacceptable. In that rule, EPA noted that continued use of these HCFCs would contribute to unnecessary depletion of the ozone layer and delay the transition to substitutes that pose lower overall risk to human health and the environment. EPA allowed existing users to continue use for a limited time to ensure that they could adjust their manufacturing processes to safely accommodate the use of other substitutes.

H. Where can I get additional information about the SNAP program?

For copies of the comprehensive SNAP lists of substitutes or additional information on SNAP, refer to EPA's Web site at www.epa.gov/ozone/snap. For more information on the Agency's process for administering the SNAP program or criteria for evaluation of

substitutes, refer to the SNAP final rulemaking published March 18, 1994 (59 FR 13044), codified at 40 CFR part 82, subpart G. A complete chronology of SNAP decisions and the appropriate citations are found at www.epa.gov/ozone/snap/chron.html.

III. What actions and information related to greenhouse gases have bearing on this proposed decision to modify prior SNAP determinations?

GWP, along with other criteria, is a factor in the overall evaluation of alternatives under the SNAP program. During the past two decades, the general science on climate change and the potential contributions of greenhouse gases (GHGs) such as HFCs to climate change have become better understood.

On December 7, 2009, at 74 FR 66496, the Administrator issued two distinct findings regarding GHGs under section 202(a) of the Clean Air Act¹⁴:

- *Endangerment Finding*: the current and projected concentrations of the six key well-mixed greenhouse gases in the atmosphere — CO₂, methane (CH₄), nitrous oxide (N₂O), HFCs, perfluorocarbons (PFCs), and sulfur hexafluoride (SF₆) — threaten the public health and welfare of current and future generations.

- *Cause or Contribute Finding*: the combined emissions of these well-mixed greenhouse gases from new motor vehicles and new motor vehicle engines contribute to the greenhouse gas pollution which threatens public health and welfare.

Like the ODSs they replace, HFCs are potent GHGs.¹⁵ Though they represent a small fraction of the current total volume of GHG emissions, their warming impact is very strong because they can remain trapped in the atmosphere for up to 250+ years impacting climate change 20,000 times more powerfully than CO₂, and their emissions are projected to accelerate over the next several decades if left unregulated. In the United States, emissions of HFCs are increasing more quickly than those of any other GHGs, and globally they are increasing 10–15% annually.¹⁶ At that rate, emissions are

projected to double by 2020 and triple by 2030.¹⁷ HFCs are rapidly accumulating in the atmosphere. The atmospheric concentration of HFC-134a, the most abundant HFC, has increased by about 10% per year from 2006 to 2012, and the concentrations of HFC-143a and HFC-125 have risen over 13% and 16% per year from 2007–2011, respectively.^{18 19}

Annual global emissions of HFCs are projected to rise to about 6.4 to 9.9 Gt CO₂eq in 2050²⁰, which is comparable to the drop in annual GHG emissions from ODS of 8.0 GtCO₂eq between 1988 and 2010 (UNEP, 2011). By 2050, the buildup of HFCs in the atmosphere is projected to increase radiative forcing by up to 0.4 W m². This increase may be as much as one-fifth to one-quarter of the expected increase in radiative forcing due to the buildup of CO₂ since 2000, according to the IPCC's Special Report on Emissions Scenarios (SRES) (UNEP, 2011). To appreciate the significance of the effect of projected HFC emissions within the context of all GHGs, HFCs would be equivalent to 5 to 12% of the CO₂ emissions in 2050 based on the IPCC's highest CO₂ emissions scenario and equivalent to 27 to 69% of CO₂ emissions based on the IPCC's lowest CO₂ emissions pathway.^{21 22} Additional information concerning the peer-reviewed scientific literature and emission scenarios is available in the docket for this rulemaking.

¹⁷ Akerman, Nancy H. Hydrofluorocarbons and Climate Change: Summaries of Recent Scientific and Papers, 2013.

¹⁸ Montzka, S.A.: HFCs in the Atmosphere: Concentrations, Emissions and Impacts, ASHRAE/NIST Conference 2012.

¹⁹ NOAA data at <ftp://ftp.cmdl.noaa.gov/hats/hfcs/>.

²⁰ Velders, G. J. M., D. W. Fahey, J. S. Daniel, M. McFarland, S. O. Andersen (2009) The large contribution of projected HFC emissions to future climate forcing. *Proceedings of the National Academy of Sciences USA* 106: 10949–10954.

²¹ HFCs: A Critical Link in Protecting Climate and the Ozone Layer. United Nations Environment Programme (UNEP), 2011, 36pp

²² IPCC, 2013: Annex II: Climate System Scenario Tables [Prather, M., G. Flato, P. Friedlingstein, C. Jones, J.-F. Lamarque, H. Liao and P. Rasch (eds.)]. In: *Climate Change 2013: The Physical Science Basis. Contribution of Working Group I to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change* [Stocker, T.F., D. Qin, G.-K. Plattner, M. Tignor, S.K. Allen, J. Boschung, A. Nauels, Y. Xia, V. Bex and P.M. Midgley (eds.)]. Cambridge University Press, Cambridge, United Kingdom and New York, NY, USA.

¹⁴ The relevant scientific and technical information summarized to support the Endangerment Finding and the Cause or Contribute Finding can be found at: www.epa.gov/climatechange/Downloads/endangerment/Endangerment_TSD.pdf

¹⁵ IPCC/TEAP (2005) Special Report: Safeguarding the Ozone Layer and the Global Climate System: Issues Related to Hydrofluorocarbons and Perfluorocarbons (Cambridge Univ Press, New York).

¹⁶ UNEP 2011. HFCs: A Critical Link in Protecting Climate and the Ozone Layer. United Nations Environment Programme.

IV. What petitions has EPA received requesting a change in listing status for substitutes with a high global warming potential?

A. Summary of Petitions

EPA received three petitions requesting EPA to modify certain acceptability listings of HFC-134a and HFC-134a blends. The first petition was submitted on May 7, 2010, by Natural Resources Defense Council (NRDC) on behalf of NRDC, the Institute for Governance and Sustainable Development (IGSD), and the Environmental Investigation Agency-US (EIA). The petition requested that EPA remove HFC-134a from the list of acceptable substitutes for ODS and move it to the list of unacceptable substitutes in multiple uses. The petitioners subsequently clarified that they were requesting this change for the use of HFC-134a in new passenger cars and light-duty trucks, non-medical aerosols, and for certain refrigeration and foam blowing end-uses. In support of their petition, the petitioners identified other substitutes for use in motor vehicle air conditioning (MVAC) and other sectors, and claimed that these other substitutes present much lower risks to human health and environment than HFC-134a.

On February 14, 2011, EPA found the petition complete for MVAC in new passenger cars and light-duty vehicles and determined it was incomplete for other uses of HFC-134a. EPA noted in its response that, at a future date, the Agency would initiate a notice-and-comment rulemaking in response to the one complete aspect of the petition, noting in particular that EPA would evaluate and take comment on many factors, including, but not limited to, the timeframe for introduction of newer substitutes for MVAC systems into the automotive market and potential lead time for manufacturers of motor vehicles to accommodate substitutes. This proposed rule responds to the aspect of that petition that we found complete.

On April 26, 2012, EPA received a petition from EIA. EIA stated that, in light of the comparative nature of the SNAP program's evaluation of substitutes and given that other acceptable substitutes are on the market or soon to be available, EPA should remove HFC-134a and HFC-134a blends from the list of acceptable substitutes for uses where EPA found CFCs and HCFCs to be nonessential under section 610 of the Act. EIA also requested that the schedule for moving HFC-134a and HFC-134a blends from the list of acceptable to unacceptable

substitutes be based on the "most rapidly feasible transitions to one or more of the" acceptable substitutes for each use. The petitioner noted that initial approvals of HFC-134a for a number of end-uses occurred in the 1990s and were based on the assessment made then that (1) HFC-134a does not contribute to ozone depletion; (2) HFC-134a's GWP and atmospheric lifetime were close to those of other substitutes that had been determined to be acceptable for the end-uses; and (3) HFC-134a is not flammable, and its toxicity is low.²³ The petitioner stated that the analysis used in the listing decisions may have been appropriate in the 1990s but was no longer reflected accurately given the range of other available or potentially available substitutes at present.

In addition to petitioning EPA for action under SNAP, the petitioner requested that the section 610 Nonessential Products Ban be extended to HFC-134a and HFC-134a blends for aerosols and pressurized dispensers (including tire inflators); foam blowing agents; novelty products (including propelled plastic party streamers, web string, artificial snow, specialty paints and excrement "poop" freeze); noise horns (including marine safety noise horns, sporting event noise horns, personal safety noise horns, wall-mounted industrial noise horns used as alarms in factories and other work areas, and intruder noise horns used as alarms in homes and cars); foam and refrigerants in new domestic refrigerators and freezers and other retail stand-alone coolers and freezers; and cleaning fluids for noncommercial electronic, photographic, and other equipment.

On August 7, 2012, EPA notified the petitioner that this petition was incomplete. EPA and the petitioner have exchanged further correspondence that can be found in the docket. Although EPA has found the petition incomplete, EPA's action in this proposal may be considered responsive to certain aspects of the petitions given EPA is proposing to change the listing of certain HFCs used in aerosols and foams from acceptable to unacceptable for most uses, and proposing to place use conditions on the remaining aerosol uses.

A third petition was filed on April 27, 2012, by NRDC, EIA and IGSD. They requested that EPA:

- Remove HFC-134a from the list of acceptable substitutes for CFC-12 in household refrigerators and freezers and

stand-alone retail food refrigerators and freezers;

- Restrict the sales of SNAP-listed refrigerants to all except certified technicians with access to service tools required under existing EPA regulations;
- Adopt a standardized procedure to determine the speed of transition from obsolete high-GWP HFCs to next-generation alternatives and substitutes;
- Remove, in addition to HFC-134a, all other refrigerants with 100-year GWPs greater than 150 from the acceptable substitutes list for household refrigerators and freezers and stand-alone retail food refrigerators and freezers.

On August 7, 2013, EPA found this petition to be incomplete. EPA and the petitioner have exchanged further correspondence that can be found in the docket. Although EPA has found the petition incomplete, EPA's action in this proposal may be considered responsive to certain aspects of the petition, given EPA is proposing to change the listing of HFC-134a from acceptable to unacceptable for new stand-alone retail food refrigerators and freezers, as well as changing the listing of a number of refrigerant blends with higher GWPs for new and retrofit stand-alone retail food refrigerators and freezers.

B. How Today's Action Relates to Petitions

This action primarily recognizes a call in the President's Climate Action Plan announced June 2013:

To reduce emissions of HFCs, the United States can and will lead both through international diplomacy as well as domestic actions . . . Moving forward, the Environmental Protection Agency will use its authority through the Significant New Alternatives Policy Program to encourage private sector investment in low-emissions technology by identifying and approving climate-friendly chemicals while prohibiting certain uses of the most harmful chemical alternatives.

The Climate Action Plan also states "to reduce emissions of HFCs, the United States can and will lead both through international diplomacy as well as domestic actions." This proposed rule is part of our domestic commitment to take action now and, by doing so, also supporting efforts to secure a global HFC phasedown. For the past five years, the United States, Canada, and Mexico have proposed an amendment to the Montreal Protocol to phase down the production and consumption of HFCs. Global benefits of the proposal would yield significant reductions of over 90 gigatons of carbon dioxide equivalent CO₂eq through 2050. The United States,

²³ See, e.g., 60 FR at 31097.

the European Union, Japan and other countries are all taking actions that will promote the uptake of low-GWP alternatives and reduce use and emissions of high-GWP HFCs.

This proposal responds to the President's Climate Action Plan and also addresses certain aspects of the three petitions referred to above. First, this action responds to the one aspect of the three petitions that EPA found complete, namely petitioners' request that EPA change the listing of HFC-134a from acceptable to unacceptable in new MVACs. (See section V.B. in today's notice.) While EPA found all remaining issues in the three petitions incomplete with respect to the other end-uses, EPA has independently acquired sufficient information to address certain other requests made by the petitioners regarding listing high GWP HFCs as unacceptable. Specifically, based on our review of the aerosols, foams, and air conditioning and refrigeration sectors, we are proposing to revise the listings for a number of substitutes from acceptable to acceptable subject to use conditions, or unacceptable. (See sections V.A., V.C., and V.D. of today's notice.) These substitutes have high GWPs as compared with other available or potentially available substitutes in those end-uses and pose significantly greater risk overall to human health and the environment. EPA considers the intersection between the specific HFC or HFC blend and the particular end-use. This action does not propose that any specific HFC be unacceptable across all sectors and end-uses. EPA is also not proposing that, for any specific sector, the only acceptable substitutes are HFC-free. EPA recognizes that both fluorinated (e.g., HFCs, HFOs and non-fluorinated (e.g., HCs, CO₂) substitutes are potentially acceptable. Instead, consistent with SNAP's history and Clean Air Act (CAA) Section 612, EPA is proposing these modifications, and will consider future modifications, based on the substitutes being considered, the SNAP criteria for evaluation, and the current suite of other available and potentially available substitutes in specific sectors and end-uses.

EPA recently issued a proposed rule (July 9, 2014; 79 FR 38811) that would list as acceptable subject to use conditions a group of refrigeration and air-conditioning alternatives that have been submitted and reviewed under the SNAP program. That rule would enhance the SNAP menu of acceptable alternatives for a number of related end-uses by proposing to add several alternatives as acceptable subject to use conditions.

As noted previously, to date, EPA has considered approximately 400 alternatives. This level of development work serves as a clear demonstration of the efforts of industry to commercialize alternatives that continue to reduce overall risk and meet the needs of a wide range of consumers.

Throughout the process of our discussions with the regulated community on the SNAP related aspects of the President's Climate Action Plan, we have sought to convey our continued understanding of the role that certainty plays in enabling this robust development and uptake of alternatives. Unfortunately, some of the key strengths of the SNAP program, such as its chemical and end-use specific consideration, its multi criteria basis for action, and its petition process tend to militate against some measures that could provide more certainty, such as bright line cut offs. That being said we do believe that the proposals we are making today, and future proposals we may make, may provide some guidelines on how EPA intends to apply specific criteria in individual end-uses. In addition, we remain committed to continuing our outreach efforts and to sharing our thinking at the earliest moment practicable on any future actions we might consider. Finally, and as it relates to potential future actions that that EPA might consider under the SNAP program, the Agency continues to welcome comments and ideas on measures we might consider within the SNAP context to provide greater certainty to both producers and consumers in SNAP regulated industrial sectors.

V. What is EPA proposing for HFCs?

EPA is proposing to modify the listings from acceptable to unacceptable for certain HFCs and HFC blends in aerosol, foam blowing, and air conditioning and refrigerant end-uses where other alternatives are available or potentially available that pose overall lower risk. Per the guiding principle stated above, EPA is considering the intersection between the specific HFC or HFC blend and the particular end-use. This action does not propose that any specific HFCs be unacceptable across all sectors and end-uses. EPA is also not proposing that, for any specific sector, the only acceptable substitutes are HFC-free. EPA recognizes that both fluorinated (e.g., HFCs, HFOs) and non-fluorinated (e.g., HCs, CO₂) substitutes are potentially acceptable. Instead, consistent with SNAP's history and CAA Section 612, EPA is proposing these modifications based on the substitutes being considered, the SNAP

criteria for evaluation, and the current suite of other available and potentially available substitutes.

EPA is proposing to modify the following listings by end-use:

(1) For aerosol propellants, we are proposing to list, as of January 1, 2016

- HFC-125 as unacceptable;
- HFC-134a as acceptable, subject to use conditions, allowing its use only in specific types of technical and medical aerosols (e.g. metered dose inhalers) (and prohibiting its use in consumer aerosols); and
- HFC-227ea as acceptable, subject to use conditions, allowing its use only in metered dose inhalers.

(2) For motor vehicle air conditioning systems in newly manufactured light-duty vehicles, we are proposing to list

- HFC-134a as unacceptable starting with model year MY 2021; and
- The refrigerant blends SP34E, R-426A (also known as RS-24), R-416A (also known as HCFC Blend Beta or FRIGC FR12), R-406A, R-414A (also known as HCFC Blend Xi or GHG-X4), R-414B (also known as HCFC Blend Omicron), HCFC Blend Delta (also known as Free Zone), Freeze 12, GHG-X5, and HCFC Blend Lambda (also known as GHG-HP) as unacceptable starting with MY 2017.

(3) For new and retrofit retail food refrigeration (including stand-alone equipment, condensing units, direct supermarket systems, and indirect supermarket systems) and new and retrofit vending machines, we are proposing to list, as of January 1, 2016

- The HFC blends R-507A and R-404A as unacceptable.

(4) For new and retrofit retail food refrigeration (including direct supermarket systems and indirect supermarket systems), we are proposing to list, as of January 1, 2016

- HFC-227ea, R-407B, R-421B, R-422A, R-422C, R-422D, R-428A, and R-434A as unacceptable.

(5) For new stand-alone retail food refrigeration and new vending machines, we are proposing to list, as of January 1, 2016

- HFC-134a and certain other HFC refrigerant blends as unacceptable.

(6) For foam blowing agents, we are proposing to list, as of January 1, 2017, except where allowed under a narrowed use limit,

- HFC-134a and blends thereof as unacceptable in all foam-blowing end-uses;
- HFC-143a, HFC-245fa and HFC-365mfc and blends thereof, and the HFC blends Formacel B, and Formacel Z-6 as unacceptable in all foam blowing end-uses where they are currently listed as acceptable, except for spray foam applications; and

- The HFC blend Formacel TI as unacceptable in all foam blowing end-uses where it is currently listed as acceptable.

In general, the dates in this proposal for modifying the SNAP listings are based on information concerning the availability of alternatives with lower overall risk to human health and the environment for the end-uses considered. EPA is requesting comment on the proposed dates. As noted in the Regulatory Flexibility Act discussion in section IX of this preamble, EPA would like information on technical challenges that may exist. EPA is particularly interested in information concerning the supply of substitutes in sufficient quantities to meet the dates proposed in this action. EPA notes that several of the end-uses could be broken down further. EPA could consider adopting temporary narrowed use limits for a specific application of an end-use if the Agency determined that substitutes would be available for all but that specific application as of a particular date. For other applications in that end-use, the rule would list the substitute as unacceptable as of that date. For the specific application at issue, the rule could contain both a temporary narrowed use limit with an expiration date and a listing as unacceptable upon the expiration of the narrowed use limit. While the temporary narrowed use limit was in place, only persons using a substitute in the end-use for that specific application would be considered to not be in violation of section 612 of the CAA and EPA's SNAP regulations (40 CFR 82.174(c)). In addition, any such end user would need to comply with the requirement to analyze and document that there are no other alternatives that are technically feasible for their specific end-use. To support the adoption of a temporary narrowed use limit for a specific application of an end-use in the final rule, commenters should explain why other alternatives would not be available for the specific application of that end-use and for what period of time.

In determining whether to modify the listing decisions for substitutes based on whether other alternatives are available that pose lower risk to human health and the environment, we considered, among other things: scientific findings, information provided by the Technology and Economic Assessment Panel that supports the Montreal Protocol, journal articles, submissions to the SNAP program, the regulations and supporting dockets for other EPA rulemakings, presentations and reports presented at domestic and international conferences,

and materials from trade associations and professional organizations. The materials on which we have relied may be found in the docket for this action. Key references are highlighted in section IX of today's notice.

A. Aerosols

1. Background

The SNAP program provides listings for two aerosol end-uses: propellants and solvents. Aerosols typically use a liquefied or compressed gas to propel active ingredients in liquid, paste, or powder form. In the case of duster sprays used to blow dust and contaminants off of surfaces, the propellant is also itself the active ingredient. Some aerosols also contain a solvent, which may be used in manufacturing, maintenance and repair to clean off oil, grease, and other soils.

Historically, a variety of propellants and solvents have been available to formulators. HCs (e.g., propane, isobutane) and compressed gases (e.g., CO₂, N₂, N₂O, compressed air) have long been used as propellants. Prior to 1978, the aerosol industry predominantly used CFCs. CFCs were excellent propellants because of their ability to produce a fine spray, their non-flammability, their ability to be stored under low pressure, and their low reactivity with other ingredients. In 1978, in response to evidence regarding depletion of the earth's ozone layer, the United States banned CFC propellants. These regulations did not address HCFCs or solvent uses. For example, CFC-113 and methyl chloroform continued to be used as solvents in aerosols and HCFCs continued to be used.

Many consumer products that previously used CFC propellants were reformulated or replaced with a variety of alternatives, including not-in-kind substitutes, such as pump sprays or solid and roll-on deodorants. Aerosol propellant substitutes included HCFCs, HCs, HFCs, compressed gases, and oxygenated organic compounds. HCFCs are controlled substances under the Montreal Protocol and subject to regulation under the CAA including a phaseout of production and import under section 605(b)-(c) and use restrictions under section 605(a).

In 1993, EPA issued regulations that implemented CAA section 610's Congressionally mandated ban on the sale and distribution or offer for sale and distribution of certain non-essential products containing ozone-depleting substances (40 CFR Part 82 Subpart C). All aerosol products and pressurized dispensers containing, or manufactured

with, CFCs and HCFCs—except those specifically exempted by the regulations—are banned from sale and distribution in interstate commerce in the United States. As a result of the Nonessential Products Ban, most aerosol products have been using low-GWP alternatives with no ozone depletion potential since the early 1990s.

2. Aerosols today

Following the 1994 ban on the sale and distribution of aerosols using HCFCs, HCFC propellants were replaced with a range of alternatives including HFCs (e.g., HFC-134a, HFC-152a), HCs, compressed gases, and not-in-kind alternatives. HCFC solvents were replaced by HFC-43-10m, HFC-365mfc, HFC-245fa, HCs, oxygenated organic compounds, hydrofluoroethers (HFEs), and *trans*-dichloroethylene (typically blended with an HFC or HFE to reduce flammability of the formulation). Other acceptable low-GWP fluorinated compounds include HFOs. HFO-1234ze(E) is in use and under development for use in the aerosol industry as a propellant for manufacturing aerosol products. EPA regulations issued pursuant to CAA section 605 prohibit the use of HCFC-22 and HCFC-142b for manufacturing aerosol products. 40 CFR 82.15(g). EPA has proposed regulations addressing the use after January 1, 2015 of other HCFCs in aerosol products (e.g., HCFC-225ca/cb), as well as other provisions related to the phaseout of HCFCs under section 605 of the CAA (December 24, 2013; 78 FR 78072).

The United States aerosol industry manufactures aerosol products in the following three categories: (1) Consumer aerosols, (2) technical aerosols, and (3) medical aerosols. Consumer aerosols includes products for personal and household use. Examples include personal care products, such as: Cosmetics, hairspray, body sprays, and deodorants; automotive products such as tire inflators, auto lubricants, and brake cleaners; noise horns and safety horns; animal repellants; spray adhesives with various applications; household cleaning products; hand-held spray paint cans; eyeglass and keyboard dusters; consumer freeze sprays (e.g. chewing gum or excrement removal); air fresheners; food dispensing products; and novelty aerosols (e.g., artificial snow, plastic string, noise makers, and cork poppers).

Technical aerosols are aerosol products for sale and use solely in commercial and industrial applications, not for normal day-to-day consumer use or medical use. Technical aerosols includes industrial cleaners (e.g.,

electronic contact cleaners, brake cleaners, flux removers, degreasers); pesticides (e.g., certain wasp and hornet sprays, aircraft insecticides); a subset of dusters (e.g., for photographic negatives, semiconductor chip manufacture, specimens for observation under electron microscope); and spinnerette lubricant/cleaning sprays. Technical aerosols also includes other miscellaneous products such as industrial spray paints and document preservation sprays.

Medical aerosols are for sale and use for medical purposes and include, but are not limited to, products regulated by the U.S. Food and Drug Administration (FDA). Medical aerosols include metered dose inhalers for the treatment of asthma and chronic obstructive pulmonary disease, calamine spray, anti-fungals, wart treatments, wound care sprays, freeze or coolant spray for pain relief, spray-on "liquid" bandages, and products for removing bandage adhesives.

Some aerosols could be considered under more than one of the categories described above. For example, insect sprays include products with both commercial and consumer applications. The commercial application would include insect sprays used by utility power line workers around high tension power lines (i.e., a technical aerosol) and the consumer use would include residential household insect repellent commonly sold to homeowners (i.e., a consumer aerosol). Another example is freeze sprays which may be either consumer aerosols (e.g., food freeze sprays, animal waste sprays) or medical aerosols (e.g., wart removers, pain relievers).

Most of the demand for consumer aerosols in the United States is concentrated within household consumer products. This category has the highest production volume, reporting a 2.4% increase from 2010 to 2011 (CSPA 2012). The NAICS code that includes many personal care products (325620) is the highest grossing NAICS category of those that EPA has identified as manufacturing consumer aerosols (ICF 2014a). Some of the dominant consumer aerosols includes air fresheners, deodorants, household cleaners, and hairspray.

3. What is EPA proposing concerning aerosols?

Today's action addresses HFCs in propellants in aerosols. EPA is proposing to modify the listings for HFC-125, HFC-134a and HFC-227ea as of January 1, 2016 as follows:

- EPA is proposing to change the listing for the aerosol propellant HFC-125 from acceptable to unacceptable.
- We are proposing to list the aerosol propellant HFC-134a as acceptable, subject to use conditions allowing its use only in the following: Cleaning products for removal of grease, flux and other soils from electrical equipment or electronics; lubricants for electrical equipment or electronics; sprays for aircraft maintenance; pesticides for use near electrical wires, in aircraft, in total release insecticide foggers, or in certified organic use pesticides for which EPA has specifically disallowed all other lower-GWP propellants; mold release agents; lubricants and cleaners for spinnerettes for synthetic fabrics; duster sprays specifically for removal of dust from photographic negatives, semiconductor chips, and specimens under electron microscopes; document preservation sprays; metered dose inhalers for the treatment of asthma, chronic obstructive pulmonary disease, allergic rhinitis, and other diseases where aerosols can be used for systemic delivery through lung, nose, or other organs; wound care sprays; topical coolant sprays for pain alleviation; and products for removing bandage adhesives from skin.

- EPA is also proposing to list HFC-227ea as acceptable, subject to use conditions, allowing its use only in metered dose inhalers.

a. What other alternatives are available?

EPA is proposing to change the listing decisions for HFC-125, HFC-134a, and HFC-227ea as of January 1, 2016 because safer alternatives (i.e., chemical compounds and technological options) are available or potentially available that reduces the overall risk to human health and the environment. Other substitutes listed as acceptable propellants include HFC-152a, HFO-1234ze(E), butane, propane, isobutane, CO₂ and other compressed gases, and dimethyl ether (DME). In addition, technological options include not-in-kind alternatives such as finger/trigger pumps, powder formulations, sticks, rollers, brushes, and wipes. These alternatives have GWPs ranging from zero to 124 compared with HFC-134a's GWP of 1,430, HFC-227ea's GWP of 3,220 and HFC-125's GWP of 3,500.²⁴ All of these alternatives have an ODP of zero, are relatively low in toxicity, and are capable of remaining below their

respective exposure limits when used as aerosol propellants. In addition to GWP and climate impacts, some of the other environmental and health attributes that the SNAP program considers that differ for these alternatives include impacts on local air quality and flammability. For example, butane, propane, isobutane, and DME are VOCs as well as being flammable. Butane, propane, isobutane, and DME are defined as VOCs under CAA regulations (see 40 CFR 51.100(s)) addressing the development of state implementation plans (SIPs) to attain and maintain the national ambient air quality standards; thus, these propellants are subject to federal, state, and local regulation that may prevent their use as a propellant in aerosols in some states and counties that have nonattainment areas for ground-level ozone. HFC-125, HFC-134a, HFC-227ea, HFC-152a, HFO-1234ze(E), and the compressed gases CO₂ and N₂ are not defined as VOCs under these regulations and their use is expected to have negligible impact on ground-level ozone levels.

i. Consumer Aerosols

For consumer aerosols, there are three alternatives with lower GWPs that meet other environmental regulatory requirements: HFC-152a, which has a GWP of 124; HFO-1234ze(E) with a GWP of 6; and CO₂ with a GWP of 1. All three have GWPs significantly lower than those of the HFCs proposed to be unacceptable or subject to use conditions (range of GWPs from 1430 to 3500 for HFC-134a, HFC-227ea and HFC-125). These three substitutes also provide a range of performance based on vapor pressure, which is important because it affects the ability to propel the necessary ingredients out of the aerosol container. The vapor pressures of HFO-1234ze(E), HFC-152a, and CO₂ at 20 °C are 422 kPa, 510 kPa, and 5776 kPa, respectively.

ii. Technical Aerosols

Technical aerosols sometimes need to meet more rigorous requirements for selection because of performance demands that do not exist for most consumer aerosols. For example, nonflammable aerosols are needed for use on energized electrical circuits, where sparking can create a fire or explosion hazard. Of the different acceptable alternatives, the nonflammable options at room temperature include HFC-125, HFC-134a, HFC-227ea, HFO-1234ze(E) and compressed gases including CO₂ and N₂. At slightly higher temperatures (30 °C or 85 °F), HFO-1234ze(E) exhibits lower and higher flammability limits and

²⁴ GWP values cited in this proposal are from the IPCC Fourth Assessment Report (AR4) unless stated otherwise. Where no GWP is listed in AR4, GWP values shall be determined consistent with the calculations and analysis presented in AR4 and referenced materials.

could catch fire under specific conditions of concentration and in the presence of a high energy spark or flame. Some aerosol product formulators have expressed concern that the lower vapor pressure of HFO-1234ze(E) and the significantly higher vapor pressure of CO₂ and other compressed gases may not provide adequate performance in propelling contents of a can or in remaining within the can for technical aerosols. For comparison, the vapor pressures of HFO-1234ze(E), HFC-134a, and CO₂ at 20 °C are 422 kPa, 655 kPa, and 5776 kPa, respectively.

The conditions under which technical aerosols are often used requires non-flammability and/or specific vapor pressure be met. Based on the information available today, EPA believes it is necessary to continue to allow for HFC-134a to be used for certain technical spray applications because of these technical limitations. We are therefore proposing to list HFC-134a as acceptable subject to use conditions which would limit use to those specific applications.

HFC-134a is the propellant with the lowest GWP that can consistently meet the technical aerosol performance requirements, other environmental regulatory requirements, and is nonflammable. EPA considered whether HFC-227ea or HFC-125 should be continue to be listed as acceptable for any specific uses. However, both these HFCs have significantly higher GWPs than HFC-134a (HFC-227ea's GWP is 3220 and HFC-125's GWP is 3500). Moreover, EPA is not aware of the use of HFC-227ea in technical aerosols. Similarly, EPA is not aware of any significant use of HFC-125 in technical aerosols. Neither HFC-227ea nor HFC-125 provides greater reduction in health or environmental risk than HFC-134a.

iii. Medical Aerosols

EPA is proposing to list HFC-134a and HFC-227ea as acceptable subject to use conditions which specify that these two HFCs are acceptable for metered dose inhalers (MDIs) to ensure that there is no confusion about the ability to continue to use these HFCs in these medical aerosols. In addition, we are proposing to list HFC-134a as acceptable subject to use conditions for wound care sprays, for topical coolant sprays for pain alleviation and for products for removing bandage adhesives from skin. For medical aerosols, there are special needs for safety and low toxicity. Furthermore, in order for a substitute to be available for use in medical devices, it must first be reviewed and approved by the FDA.

FDA has approved medications for use in metered dose inhalers using HFC-134a and HFC-227ea as propellants, as well as some not-in-kind dry powder medications.

FDA has not approved medications for MDIs or other medical aerosols using HFC-125. EPA is aware of some medical aerosols that are currently using hydrocarbons or DME as the propellant, as well as not-in-kind alternatives; these medical aerosols include antifungals, calamine sprays, freeze sprays for wart removal, and liquid bandages (ICF, 2014a). EPA has insufficient information that alternatives other than HFC-134a are available as propellants in wound care sprays; topical coolant sprays for pain alleviation; and products for removing bandage adhesives from skin. Therefore, we cannot conclude that these are available alternatives with less overall risk to human health and the environment than HFC-134a. For these reasons, we are proposing to list HFC-227ea as acceptable subject to a use condition limiting its use to MDIs and to list HFC-134a as acceptable subject to use conditions limiting its use to MDIs and the other medical uses listed above.

HFC-125 has a GWP of 3,500, which is higher than the GWP of all other alternatives that are available for use as aerosol propellants (HFC-227ea has a GWP of 3220; HFC-134a has a GWP of 1430; HFO-1234ze(E) has a GWP of 6). Like HFC-134a, HFC-227ea, CO₂ and HFO-1234ze(E), it is VOC-exempt, nonflammable and low in toxicity. When EPA listed HFC-227ea as acceptable (May 22, 1998; 63 FR 28251), EPA noted that it was doing so despite the relatively high GWP of this compound, because it fit a specialized application, metered dose inhalers, where other substitutes were not available that would provide acceptable performance.

EPA's proposed approach to restricting the use of HFC-134a and HFC-227ea only to manufacturing certain specific types of aerosol products is modeled upon the Nonessential Product Ban exemptions for ODS in subpart C of 40 CFR part 82. A difference between that ban and the proposed use conditions is that the Nonessential Products Ban addressed the *sale and distribution* or offer for sale and distribution of aerosol products in interstate commerce, whereas this proposal addresses the propellants that may be *used in manufacturing* aerosol products.

Today, EPA is proposing to list HFC-125 as unacceptable, HFC-227ea as acceptable subject to use conditions allowing its use only for MDIs and

HFC-134a as acceptable subject to use conditions allowing its use only for specific technical and medical aerosols, including MDIs. We request comment on this approach to modifying the listings of these three HFCs. We also request comment on whether any of the proposed technical aerosol uses of HFC-134a should not be allowed or whether there are additional uses that should be added to the list of allowed uses under the use conditions. Through this action, EPA is not intending to alter the listing as acceptable for HFC-227ea and HFC-134a for metered dose inhalers. EPA is seeking comment on the additional medical and technical aerosol uses of HFC-134a.

b. What other approaches is EPA considering?

EPA is considering two approaches to changing the listings for aerosols and seeks comments on both. The first, as discussed above, is to find HFC-125 unacceptable and find HFC-227ea and HFC-134a acceptable subject to use conditions, where the use conditions specify a list of allowed uses or product types that may continue to use these HFCs (e.g., metered dose inhalers for both HFCs, insect sprays used near high tension power lines for HFC-134a). A second approach we are considering is to find HFC-125 unacceptable and to find HFC-134a acceptable subject to narrowed use limits in technical and medical aerosols and HFC-227ea subject to narrowed use limits in metered dose inhalers. Narrowed use limits are considered "use restrictions" and are explained above. In this case, only persons using HFC-227ea in metered dose inhalers or using HFC-134a in technical or medical aerosols would be considered to not be in violation of section 612 of the CAA and EPA's SNAP regulations (40 CFR 82.174(c)). The terms "technical aerosol" and "medical aerosol" would apply to the types of aerosols described above in section 2. "Aerosols today." Under the narrowed use limits, a manufacturer or other user intending to use the substitute could only use HFC-134a in manufacturing a technical or medical aerosol, or HFC-227ea in manufacturing a metered-dose inhaler, after ascertaining that other alternatives are not technically feasible. The user also would be required to document their evaluation. 40 CFR 82.180(b)(3).

Advantages to the proposed approach of specifying the allowed uses are that the list is clear about which products are allowed to use HFC-134a or HFC-227ea, both for users and for EPA. In addition, because EPA is specifying the uses in advance, end-users would not be

required to perform an evaluation and would not be required keep paperwork to document their evaluation, thereby reducing regulatory burden. A potential advantage of setting narrowed use limits is that it may encourage a larger number of manufacturers and users to evaluate alternatives and potentially identify more uses where HFC-134a is not required. Further, establishing narrowed use limits may allow greater flexibility if there are additional types of technical or medical aerosol products with performance or safety constraints requiring HFC-134a that EPA has not identified in this proposal. EPA requests comment on these two approaches to modifying the listings of HFC-134a and HFC-227ea as aerosol propellants.

c. When would the modified listings apply?

EPA is proposing January 1, 2016 as the date on which the listings for HFC-125, HFC-134a and HFC-227ea would be modified. Thus products manufactured on or after January 1, 2016 in contravention of the unacceptable or acceptable subject to use conditions listing for these substitutes could not be used.

We are proposing this date because we believe it is expeditious but will allow sufficient time after this proposed rule for end users to make the transition to alternatives. Based on the information available to EPA today and on various discussions with industry representatives, EPA believes that formulators and packagers of aerosols can make the necessary changes within this timing (ICF, 2014a; Honeywell, 2014). In most cases, EPA believes it will take approximately six months for the necessary changes to be made. This timing would provide the affected aerosol manufacturers and packagers sufficient time to change and test formulations and, to the extent necessary, to change the equipment in their factories.

To prevent stranded inventory, we are proposing that products manufactured prior to January 1, 2016 using these propellants, could be still be sold, imported, exported, and used by the end user after January 1, 2016. This would avoid the possibility that end users would need to dispose of a usable product, including the potential for improper releases of the content into the environment.

d. On which topics is EPA requesting comment?

EPA requests comment on the proposal to change the listing for the following aerosol propellants: HFC-125 from acceptable to unacceptable; HFC-134a from acceptable to acceptable,

subject to use conditions allowing its use only in: cleaning products for removal of grease, flux and other soils from electrical equipment or electronics; lubricants for electrical equipment or electronics; sprays for aircraft maintenance; pesticides for use near electrical wires, in aircraft, in total release insecticide foggers, or in certified organic use pesticides for which EPA has specifically disallowed all other lower-GWP propellants; mold release agents; lubricants and cleaners for spinnerettes for synthetic fabrics; duster sprays specifically for removal of dust from photographic negatives, semiconductor chips, and specimens under electron microscopes; document preservation sprays; metered dose inhalers for the treatment of asthma, chronic obstructive pulmonary disease, allergic rhinitis, and other diseases where aerosols can be used for systemic delivery through lung, nose, or other organs; wound care sprays; topical coolant sprays for pain alleviation; and products for removing bandage adhesives from skin; and HFC-227ea from acceptable to acceptable, subject to use conditions, allowing its use only in metered dose inhalers.

EPA also received suggestions from the aerosol industry to consider an exception to allow the use of HFC-134a in additional categories of aerosol products. EPA is not proposing to include these categories, either because we are aware of existing products in these categories using low GWP propellants, or because we have insufficient information indicating that the use of HFC-134a is necessary for these categories of products because other substitutes that pose lower risk are not currently or potentially available. These categories include: component freeze sprays, tissue freezes, refrigeration system flushes, portable safety horns for use in marine and industrial applications, tire inflators, and personal defense sprays. We are aware of low-GWP formulations already on the market today for defensive sprays and tissue freezes. These formulations may use flammable and/or non-flammable propellants. We request information on why available substitutes other than HFC-134a are not and cannot be used in these categories of products, including information on why flammability may be a concern or not in the product category; whether other alternative propellants with lower GWP in place of HFC-134a have been tested in these products; and what results of those tests have shown about the technical feasibility and/or safety of the other alternative propellants.

Finally, we request comments on modifying the listings as of January 1, 2016. We request commenters include specific information on whether it would be technically feasible for end-users to transition by January 1, 2016, and, if not, what steps are necessary for manufacturers to switch to other alternatives and how long those steps are expected to take.

B. Motor Vehicle Air Conditioning for Newly Manufactured Light-Duty Motor Vehicles

1. Background

MVAC systems cool passenger cars, light duty trucks, buses, and rail vehicles. CFC-12 refrigerant was historically used in MVAC systems. HFC-134a replaced CFC-12 in new equipment in the early 1990s. Today, HFC-134a is the dominant refrigerant used in light-duty vehicles worldwide. When EPA found HFC-134a acceptable in MVAC for light duty vehicles in 1994 (March 18, 1994; 59 FR 13044), the Agency stated:

HFC-134a does not contribute to ozone depletion. HFC-134a's GWP and atmospheric lifetime are close to those of other alternatives which have been determined to be acceptable for this end-use. However, HFC-134a's contribution to global warming could be significant in leaky end-uses such as MVACs. EPA has determined that the use of HFC-134a in these applications is acceptable because industry continues to develop technology to limit emissions. In addition, the number of substitutes available for use in MVACs is currently limited. HFC-134a is not flammable and its toxicity is low.

This analysis was consistent with the information available in 1994. Since that time, four additional substitutes have been added to the list of substitutes that are acceptable subject to use conditions for light duty vehicles. As described more fully below, if these other substitutes are used in systems designed consistent with the prescribed use conditions, they pose significantly lower risk to human health and the environment than HFC-134a. EPA is therefore proposing to remove HFC-134a from the list of acceptable substitutes for new light-duty vehicles' MVAC systems and add it to the list of unacceptable substitutes.

Since 1994, additional alternatives for MVACs have been listed as acceptable subject to use conditions.²⁵ Three of these alternatives—HFO-1234yf, HFC-152a, and carbon dioxide (R-744)—are non-ozone depleting like HFC-134a and have low GWPs compared to HFC-134a. HFC-152a has a GWP of 124, HFO-1234yf has a GWP of 4, and R-744 (by

²⁵ Listed at 40 CFR part 82, subpart G.

definition) has a GWP of 1 while HFC-134a has a GWP of 1,430. R-744 is nonflammable, HFO-1234yf and HFC-152a are flammable, but are subject to use conditions that address flammability concerns. All three substitutes are subject to use restrictions that ensure exposure limits that protect against adverse health effects will not be exceeded and all three are VOC exempt.

At the time EPA listed HFC-134a as acceptable, the agency was not aware of any vehicle manufacturer, MVAC supplier, or chemical producer considering HFO-1234yf as a refrigerant. Today, HFO-1234yf is in use in MVAC systems in approximately nine²⁶ models in the United States by several manufacturers of light-duty vehicles. EPA expects additional models will be introduced using HFO-1234yf systems over the next several years.

To date, at least one global manufacturer of light-duty vehicles has announced their intention to commercialize vehicles using R-744 in MVAC systems later this decade.²⁷ In the mid-1990s, EPA became aware that R-744 systems might be a feasible alternative in this application, but the state of research and development indicated that it was not yet available because a design had not yet been developed that would allow safe use in MVAC systems in light duty vehicles. Nearly 20 years later, EPA is still not aware of current commercial use of R-744 in MVAC systems. However, significant research and development is occurring in order to ensure R-744 can be used safely in MVAC systems.

In addition to HFO-1234yf, HFC-152a, and R-744, EPA is aware of ongoing research and development which could ultimately result in future listings of additional alternatives for MVAC systems. One chemical producer indicated their intent to seek SNAP approval for another low-GWP alternative that is a blend with a GWP below 150.²⁸

There are also other blends which EPA has listed as acceptable or acceptable subject to use conditions. None of these are currently used by the original equipment manufacturers (OEMs). Several of these previously listed substitutes have GWPs that are significantly higher than the GWPs for HFO-1234yf, HFC-152a, and R-744 and higher overall risk than these other three substitutes. EPA is proposing to list as unacceptable the following substitutes

in addition to HFC-134a: SP34E (GWP of 1300), R-426A (also known as RS-24) (GWP of 1508), R-416A (also known as HCFC Blend Beta or FRIGC FR12) (GWP of 1015) and the HCFC blends, R-406A, R-414A (also known as HCFC Blend Xi or GHG-X4), R-414B (also known as HCFC Blend Omicron), HCFC Blend Delta (also known as Free Zone), Freeze 12, GHG-X5, and HCFC Blend Lambda (also known as GHG-HP), with GWPs ranging from 1480 to 2340 and ODPs ranging from 0.012 to 0.056. For simplicity, we refer to these substitutes as “the refrigerant blends” in the following discussion.

2. What is EPA proposing regarding use of HFC-134a and use of refrigerant blends in MVAC systems for newly manufactured light-duty motor vehicles?

EPA is proposing to list HFC-134a as unacceptable for use in MVAC systems in newly manufactured light-duty vehicles beginning with MY 2021. We are proposing MY 2021 because that is the time by which all light-duty vehicle models can be redesigned to safely use MVAC systems using other available refrigerants. As explained above, three alternatives on the SNAP list of acceptable substitutes subject to use conditions—HFC-152a, R-744, and HFO-1234yf—have significantly lower GWPs than HFC-134a. All three of these lower-GWP alternatives are non-ozone depleting and are subject to use restrictions that ensure exposure limits that protect against adverse health effects will not be exceeded. All three are VOC exempt. HFO-1234yf and HFC-152a are flammable, but are subject to use conditions that address flammability concerns. R-744 is not flammable. Because HFC-134a has a significantly higher GWP than HFC-152a, R-744, and HFO-1234yf and because the risks posed by these three refrigerants are addressed through use conditions, we are proposing to list HFC-134a as unacceptable. However, because the three refrigerant alternatives pose lower risk than HFC-134a only if used consistent with the established use conditions, in deciding when the unacceptability determination should apply, we considered the date by which automobile manufacturers will be able to redesign all vehicle models (including design of the MVAC systems) consistent with the use conditions.

EPA is proposing to list the refrigerant blends SP34E, R-426A, R-416A, R-406A, R-414A (also known as HCFC Blend Xi or GHG-X4), R-414B (also known as HCFC Blend Omicron), HCFC Blend Delta (also known as Free Zone), Freeze 12, GHG-X5, and HCFC Blend

Lambda (also known as GHG-HP) as unacceptable beginning in MY 2017 for use in MVAC systems in newly manufactured light-duty motor vehicles. Since these refrigerant blends are not currently in use in any MVAC systems in light-duty vehicles, we believe it is appropriate for the unacceptability determination to apply to model year vehicles currently being designed. Further, all but the first two of these blends have ODPs, and all have significantly higher GWPs than other alternatives such as HFC-152a, HFO-1234yf, and CO₂.

EPA has previously examined when automobile manufacturers may be able to transition their fleets to lower GWP refrigerants in its rules to extend the greenhouse gas and fuel economy standards for model year (MY) 2017–2025 light-duty vehicles. 77 FR 62624, 62807–810 (October 15, 2012); see also 75 FR 25325, 25431–32 (May 7, 2010) (discussing the same issue for MY 2012–2016 light-duty vehicles). EPA and the National Highway Traffic Safety Administration jointly issued these rules on August 28, 2012. Over the lifetime of the MY 2017–2025 light-duty vehicles (passenger cars, light-duty trucks, and medium-duty passenger vehicles), these rules are projected to save approximately 4 billion barrels of oil and 2 billion metric tons of GHG emissions, with societal net benefits up to \$451 billion. 77 FR 62629. The standards build off those set in April 2010 for MY 2012–2016 light-duty vehicles, which are projected to save approximately 1.85 billion barrels of oil and 962 million metric tons of GHG emissions over the lifetime of the affected vehicles, with societal net benefits of up to \$192 billion. 75 FR 25347. EPA projects that the entire light-duty vehicle fleet will meet a target of 163 grams of carbon dioxide equivalent (CO₂eq) per mile in MY 2025 (or 54.5 mpg if the automotive industry meets the target exclusively through fuel efficiency improvements).

When refrigerants leak from current motor vehicle air conditioning systems, they contribute to overall GHG emissions. Using lower GWP refrigerants can significantly reduce the climate impact of these emissions. Given the increasing availability of lower-GWP chemicals suitable for this purpose and systems that can use them, as well as increasing requirement for lower-GWP refrigerants in Europe,²⁹ EPA based the light-duty GHG standards

²⁶ <http://www.autonews.com/article/20131230/OEM01/312309996/warming-to-the-idea>.

²⁷ Daimler, 2014

²⁸ Mexichem statement during motor vehicle stakeholder meeting December 6, 2013

²⁹ Directive 2006/40/EC of the European Parliament and of the Council of 17 May 2006 (EU MAC Directive). Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006L0040:EN:HTML>.

for MYs 2017–2025 in part on an expected gradual transition to lower-GWP refrigerants. Thus, in setting the level of the standards, EPA projected that the industry will make the full transition to lower-GWP refrigerants over the period of time spanning between MY 2017 and MY 2021, and the level of the standard in each of these model years reflects a projected 20 percent increase in substitution in each model year and complete transition by MY 2021. 77 FR 62720/2–3. In support of the assumption of this multi-year transition, the Light-Duty GHG rule for MYs 2017–2025 includes an extensive discussion of the refrigerant substitute availability and technical feasibility of transitioning the fleet. 77 FR 62720; 62807–810.

At the time the Light Duty GHG rule was promulgated, EPA (and other entities) voiced concerns with the potential supply of HFO–1234yf, but today production plans for the refrigerant appear to be in place to make it available in volumes that meet current and projected domestic auto industry demand, consistent with the projections in the Light Duty GHG rulemaking. Multiple production facilities are now producing HFO–1234yf, and recently another global chemical producer announced plans to produce HFO–1234yf by 2017. Moreover, some automotive manufacturers are developing systems that can safely use other substitutes, including R–744, and continued progress is likely given the EU's implementation of the MAC Directive. If some global light-duty motor vehicle manufacturers use R–744, additional volumes of HFO–1234yf that would have been used by those manufacturers will then become available. Therefore, there also appears to be sufficient supply to meet demand domestically and abroad, including in the European Union, during this time frame.

In addition to considering when the supply of alternative refrigerants would be sufficient to transition the entire light duty vehicle fleet, EPA necessarily also considered when vehicle manufacturers could design systems for safe use of these alternatives consistent with the regulatory use conditions.³⁰ EPA considered the practices used by the auto manufacturing industry in introducing new technologies into their vehicles. For each vehicle model, manufacturers establish a “redesign” (or product development) cycle over which

they plan any significant technological changes to that vehicle. Between the major redesign model years, they may make only minor “refresh” changes. Redesign cycles vary by model and by manufacturer and average about 5 model years in duration. (See 77 FR 62712 and 75 FR 25407, 25451 for a more detailed discussion of this practice.) At any point in time, a manufacturer may have some vehicles at or approaching a major redesign point and others that are earlier in their product cycle.

In the final rule establishing light-duty vehicle GHG standards for MYs 2017–2025, EPA assumed that the transition to alternative refrigerants would generally occur during manufacturer model redesigns and used the overall typical industry redesign cycle of 5 model years to estimate how the expected industry-wide transition to new refrigerants might occur. For analytical purposes, and based on information available at the time, we projected that the transition would occur from MY 2017 until MY 2021. EPA recognizes there have been some early adopters. The transition began in a small number of MY 2013 vehicles and is increasing in MY 2014 but has been relatively limited to date.³¹ While some may maintain that early adoption equates to a faster overall transition, EPA notes that early adoption remains limited and therefore we continue to view our projection of full transition not occurring until MY 2021 as reasonable.

Although there may be some limited ability to switch a vehicle model to an MVAC system using a low GWP refrigerant in between redesign periods, most model types will require significant hardware changes that may only be possible during a redesign. HFO–1234yf, for example, has measurably lower efficiency than that of HFC–134a, usually requiring hardware changes and/or changes to overall air conditioning system design and layout.^{32 33} This contrasts with the case

of the transition in the 1990s from CFC–12 to HFC–134a, where the systems had similar coefficients of performance and manufacturers were able to switch many vehicles mid-cycle. Vehicles that require relatively more cooling capacity will be more dependent on a redesign cycle for a transition to HFO–1234yf since the specifications for hardware would need to be revisited. Most manufacturers have “locked-in” their planned product designs out to MY 2016, MY 2017, or even MY 2018. If any of these manufacturers have not planned to implement alternative refrigerant systems in these late model year vehicles, the next design cycle opportunity to make a change would be unlikely to occur until MY 2021 (or even MY 2022). In addition, at least one manufacturer has stated that it plans on using R–744 (CO₂) systems. R–744 systems require significantly more complex redesign and hardware and would need to occur during product redesign, not product refresh given its pressure is significantly different than HFC–134a. These systems are currently in prototype phase, and there are significant technical hurdles yet to overcome. Given EPA's understanding, above, of the supply of the alternative refrigerants and the redesign cycle for MVAC systems, EPA is proposing to list HFC–134a as unacceptable for new MVAC systems beginning with MY 2021 because this is the time by which all light-duty vehicle models can be redesigned to safely use MVAC systems with alternative refrigerants.

As a cross-check, EPA explored whether vehicles and MVAC systems designed consistent with the use conditions for the three alternative refrigerants might be available earlier than MY 2021, evaluating (but not proposing) MYs 2017 and 2019. MY 2017 is the date included in the petition described above and in the EU MAC Directive. Since most motor vehicle manufacturers will seek a global vehicle design platform, selecting the same date as the date in the EU MAC Directive has some weight. MY 2019 is an intermediate date between MYs 2017 and 2021.

The agency believes it is necessary for MVAC system redesigns for many vehicles to occur during a design cycle to safely use the substitute refrigerants, as just explained. Manufacturers are currently designing or have “locked in” designs for vehicles several model years into the future. The information currently before the Agency thus indicates that it would not be

³⁰ As previously noted, HFO–1234yf, R–744 and HFC–152a are all listed as acceptable subject to use conditions and many of the use conditions address the design of systems to account for the flammability or exposure.

³¹ Nelson, Gabe “Automakers’ switch to new refrigerant will accelerate with EPA credits, European mandate” *Automobile News*, December 30, 2013. <http://www.autonews.com/article/20131230/OEM01/312309996/warming-to-the-idea>.

³² Weissler, Paul, “A/C Industry Faces Challenges From Daimler R–1234yf Issue, Explores Other Options,” *Automotive Engineering International*, April 2, 2013.

³³ One manufacturer informed EPA in a meeting that hardware changes were necessary or likely when shifting from a HFC–134a to a HFO–1234yf system, including the following: compressor oil and/or compressor changes, possible A/C piping modification due to the change in valve shape, and, in the vehicle manufacturing plant, additional refrigerant charging process changes. (EPA Memorandum: “Notes from Meeting with Nissan Concerning Alternative Refrigerant Transition”, Tad

Wysor, April 2014.) Other manufacturers made similar statements to EPA.

technically feasible for manufacturers to safely transition all vehicles from HFC-134a MVACs by MY 2017. EPA is not proposing the MY 2019 date for the same reasons. However, we solicit comment on whether all manufacturers would be able to safely transition all vehicles away from HFC-134a MVAC systems by MY 2017 or MY 2019.

We also considered whether a MY later than MY 2021 should be the appropriate time for use of HFC-134a in MVAC systems in new vehicles to be listed as unacceptable. In recent meetings with the major trade associations for the auto industry (the Alliance and Global Automakers) as well as with meetings with several individual manufacturers, industry representatives indicated that some of them may have a relatively small number of vehicle models that will not have had the opportunity for an engineering redesign by MY 2021. They also indicated that there may be technical barriers for certain models that would require longer product design cycles if the systems were to use substitute refrigerants. However, we do not have sufficient non-confidential information to conclude that systems capable of using alternative refrigerant safely will not be “currently or potentially available”—within the meaning of section 612 (c)(2) of the Act—until after MY 2021. EPA requests comments on changing the status of HFC-134a in a model year later than MY 2021 (such as MY 2025), including specific information supporting claims that a transition by MY 2021 would not be technically feasible because specific model vehicles cannot be redesigned to safely use alternative refrigerants by MY 2021. For the reasons explained earlier, EPA believes safer alternatives will be available by MY 2021.

Based on the information before the Agency, EPA is thus proposing to modify the listing of HFC-134a to unacceptable as of MY 2021 for light duty vehicles, while seeking comment on MYs 2017, 2019, and MYs later than 2021.³⁴

EPA is not proposing changes that would alter the ability to service existing motor vehicles designed to use HFC-134a. Such a change could strand the installed base of equipment or force retrofits to other refrigerants. In order to safely use most MVAC refrigerants, the

vehicle design as well as the MVAC design may need to be modified in order to ensure the refrigerant can be used safely. For that reason, the three low-GWP refrigerants that currently are listed as acceptable in new MVACs—HFO-1234yf, HFC-152a, and R-744—are not listed as acceptable to retrofit a system designed to use a different refrigerant.

Once MVAC systems are designed and installed with lower GWP substitutes, they will likely need to be serviced. Some stakeholders have expressed a concern that the price differential between HFO-1234yf and HFC-134a provides an economic incentive to replace HFO-1234yf with HFC-134a during servicing. See 77 FR 62807. Two sets of regulations under title VI of the CAA make it clear that doing so is unlawful. First, the SNAP regulations prohibit using a substitute refrigerant to “top-off” a system that uses another refrigerant. Second, the original refrigerant must be recovered in accordance with regulations issued under section 609 of the CAA prior to charging with a substitute (40 CFR 82.34). Thus, the recycling and recovery regulations prohibit adding a new refrigerant to the system without first recovering the refrigerant already in the system. Therefore, it is not permissible to add HFC-134a to an MVAC system that contains HFO-1234yf, as may well occur if a consumer were to service his or her own car’s A/C system without refrigerant recovery equipment. In addition, the SNAP listings for HFO-1234yf and HFC-134a require the use of unique fittings for each alternative refrigerant. Using an adapter or deliberately modifying a fitting to use a different refrigerant is a violation of these use conditions.

EPA seeks comments on changing the listing of SP34E, R-426A, R-416A, R-406A, R-414A (also known as HCFC Blend Xi or GHG-X4), R-414B (also known as HCFC Blend Omicron), HCFC Blend Delta (also known as Free Zone), Freeze 12, GHG-X5, and HCFC Blend Lambda (also known as GHG-HP) to unacceptable for use as refrigerants in air conditioning systems for newly manufactured light-duty motor vehicles beginning with MY 2017 and changing the listing of HFC-134a to unacceptable beginning with MY 2021.

3. Would this action affect EPA’s light duty vehicle rule?

Today’s proposal, should EPA adopt it, will have no direct effect on the MY 2017–2025 light duty vehicle GHG standards. Those standards are established by rule and EPA is not reopening that rule in this proceeding.

We do note, however, that today’s proposal is relevant to one of the compliance flexibilities in the light duty vehicle standards. The light duty vehicle standards do not require any specific means of compliance. Manufacturers thus have the flexibility to either switch refrigerants or to comply with the standards by other means. The light duty standards do provide that manufacturers can generate credits from use of alternative refrigerants with lower GWPs than that of HFC-134a through MY 2025, and the ability to generate and use those credits towards compliance with the light duty standards will not change if this action is finalized as proposed. See 77 FR 62804–809. (As noted above, the level of the standard reflects the assumption of 100% substitution by MY 2021). Even though a manufacturer may choose to comply with the light duty standard by a strategy not involving refrigerant substitution, in MY 2021, this proposed rule, if finalized, would still require the manufacturer to use an MVAC designed for a refrigerant other than HFC-134a.

C. Retail Food Refrigeration and Vending Machines

1. Background

Retail food refrigeration, an end-use within the SNAP program that is also considered a subset of the broader term “commercial refrigeration,” is characterized by storing and displaying, generally for sale, food and beverages at different temperatures for different products (e.g., chilled and frozen food). The designs and refrigerating capacities of equipment vary widely. Vending machines are another subset of commercial refrigeration considered as a separate end-use within the SNAP program due to differences in where such equipment is placed and the additional mechanical and electronic components required to accept payment, provide the selected product, and prevent theft or damage from vandalism.

Retail food refrigeration is composed of three main categories of equipment: Stand-alone equipment; condensing units; and supermarket systems, the latter often in designs referred to as multiplex or centralized refrigeration systems. Stand-alone equipment consists of refrigerators, freezers, and reach-in coolers (either open or with doors) where all refrigeration components are integrated and, for the smallest types, the refrigeration circuit is entirely brazed or welded. These systems are charged with refrigerant at the factory and typically require only an electricity supply to begin operation.

³⁴ Typically, regulations promulgated under CAA Title VI have applied to specified calendar years. However, because the MVAC system used is so closely related to vehicle design, we have used MY for purposes of this proposed rule. Model years cover almost two calendar years, beginning after January 1 of the previous calendar year and ending on January 1 of the following calendar year.

Condensing units exhibit refrigerating capacities ranging typically from 1 kW to 20 kW (0.3 to 5.7 refrigeration tons). They are composed of one (and sometimes two) compressor(s), one condenser, and one receiver assembled into a single unit, which is normally located external to the sales area. This equipment is connected to one or more nearby evaporator(s) used to cool food and beverages stored in display cases and/or walk-in storage rooms. Condensing units are commonly installed in convenience stores and specialty shops such as bakeries and butcher shops.

Typical supermarket systems are known as multiplex or centralized systems. They operate with racks of compressors installed in a machinery room; different compressors turn on to match the refrigeration load necessary to maintain temperatures. Two main design classifications are used: Direct and indirect systems. In the United States, direct systems are the most widespread. At least 70 percent of supermarkets in the United States use centralized direct expansion (DX) systems to cool their display cases.³⁵ The refrigerant circulates from the machinery room to the sales area, where it evaporates in display-case heat exchangers, and then returns in vapor phase to the suction headers of the compressor racks. The supermarket walk-in cold rooms are often integrated into the system and cooled similarly, but an alternative option is to provide a dedicated condensing unit for a given storage room. Another type of supermarket design, often referred to as a distributed refrigeration system, uses an array of separate compressor racks located near the display cases rather than having a central compressor rack system. Each of these smaller racks handles a portion of the supermarket load, with 5–10 such systems in a store.

Indirect supermarket designs include secondary loop systems and cascade refrigeration. Indirect systems use a chiller or other refrigeration system to cool a secondary fluid that is then circulated throughout the store to the cases. Compact chiller versions of an indirect system rely on a lineup of 10–20 units, each using small charge sizes. As the refrigeration load changes, more or fewer of the chillers are active. Compact chillers are used in a secondary loop system whereby the chillers cool a secondary fluid that is then circulated throughout the store to the display cases. Each compact chiller is an independent unit with its own

refrigerant charge, reducing the potential for refrigerant to be released from leaks or catastrophic failures. Cascade systems use a compressor to raise the low-temperature coolant from low-temperature conditions up to an intermediate temperature while a separate refrigerant system uses a different refrigerant to condense the coolant. Each system within the cascade design contains its own refrigerant charge allowing the use of different refrigerants in each system. This application has generally used a low-GWP refrigerant, specifically carbon dioxide (R-744), in the low-temperature system, with a variety of refrigerants in the medium-temperature system.

Refrigerant choices depend on the refrigerant charge, the temperature required, and energy efficiency, among other things. In addition to regulations pursuant to the SNAP program, other federal or local regulations may also affect refrigerant choice. For instance, regulations from the OSHA may restrict or place requirements on the use of some refrigerants, such as ammonia (R-717). Building codes from local and State agencies may also incorporate limits on the amount of particular refrigerants used. There are and will continue to be a number of factors that retailers must consider when selecting the refrigerant and operating system design. While a number of approaches exist, there is no uniformly accepted holistic analysis of the multiple factors, which include the following: Energy efficiency; system performance; potential impact on community safety; ambient temperatures; potential risk to personal safety; cost; and minimization of direct and indirect environmental impacts. EPA recognizes that these and other factors mean there will be a range of options, and the ultimate selection remains with the owner and operator of the system.

Acceptable non-HFC substitutes in use today for new multiplex systems include R-717 and R-744. These can be used alone or in combination with other refrigerants in other parts of the equipment, depending on the equipment and its design (e.g., a secondary-loop contains one refrigerant while the primary loop contains a different refrigerant). For stand-alone refrigeration equipment, propane (R-290) is listed as acceptable subject to use conditions, and EPA has also proposed that the hydrocarbon blend R-441A and isobutane (R-600a) be listed as acceptable subject to use conditions (July, 9, 2014; 79 FR 38811). The Agency also has proposed elsewhere that these three hydrocarbon refrigerants be listed as acceptable subject to use

conditions for vending machines (July, 9, 2014; 79 FR 38811). Other substitutes, such as blends of saturated HFCs already listed as acceptable under SNAP, are currently in use in the United States, while HFOs and blends containing HFOs are being developed and tested but have not yet been submitted to the SNAP program for review.

The most commonly-used HFCs and HFC blends in retail food refrigeration include HFC-134a, R-404A, R-407A, R-422D, and R-507A. HFC-134a is a non-ozone depleting chemical with the chemical formula $C_2H_2F_4$. It is used in a variety of air-conditioning and refrigeration end-uses, including motor vehicle air conditioners, home appliances (such as refrigerator-freezers), vending machines and building air-conditioning chillers. It is also used in other sectors such as foam blowing and aerosol propellants. HFC-134a has a GWP of 1,430.

R-404A is a non-ozone depleting blend of refrigerants HFC-125, HFC-143a, and HFC-134a with GWPs of 3,500, 4,470, and 1,430 respectively. R-404A's GWP is about 3,920 based on the 44/52/4 mass percentages of the three HFCs contained in the blend. R-404A is currently acceptable for a variety of medium- and low-temperature refrigeration applications including retail food refrigeration equipment such as food display and storage cases; vending machines; cold storage warehouses; commercial ice machines; refrigerated transport; and industrial process refrigeration.

R-407A is a non-ozone depleting blend of refrigerants HFC-32, HFC-125 and HFC-134a with GWPs of 675, 3,500, and 1,430 respectively. R-407A's GWP is about 2,100 based on the 20/40/40 mass percentages of the three HFCs contained in the blend. R-407A is acceptable for a variety of medium- and low-temperature refrigeration applications including retail food refrigeration equipment such as food display and storage cases; cold storage warehouses; commercial ice machines; refrigerated transport; and industrial process refrigeration. R-407A is not currently on the SNAP lists of acceptable or unacceptable refrigerants for vending machines.

R-422D is a non-ozone depleting blend of refrigerants HFC-125, HFC-134a, and R-600a with GWPs of 3,500, 1,430, and 8 (GE, 2008) respectively. R-422D's GWP is about 2,700 based on the approximate 65.1/31.5/3.4 mass percentages of the two HFCs and one hydrocarbon contained in the blend. R-422D is acceptable for a variety of medium- and low-temperature

³⁵ <http://www2.epa.gov/greenchill/advanced-refrigeration>.

refrigeration applications including retail food refrigeration equipment such as food display and storage cases; cold storage warehouses; commercial ice machines; refrigerated transport; and industrial process refrigeration. R-422D is most commonly used to retrofit existing systems such as those operating on HCFC-22 and is less likely to be used in manufacturing new equipment.

R-507A (also designated as R-507) is a non-ozone depleting blend of refrigerants HFC-125 and HFC-143a which have GWPs of 3,500 and 4,470, respectively. R-507A's GWP is about 3,990 based on the 50/50 mass percentages of the two HFCs contained in the blend. R-507A is acceptable for a variety of medium- and low-temperature refrigeration applications including in retail food refrigeration equipment such as food display and storage cases; cold storage warehouses; refrigerated transport; and industrial process refrigeration.

2. What is EPA proposing for new and retrofit retail food refrigeration (condensing units and supermarket systems)?

EPA is proposing to change the listing for nine HFC blends for new and retrofit retail food refrigeration equipment from acceptable to unacceptable as of January 1, 2016. These nine blends are R-404A, R-407B, R-421B, R-422A, R-422C, R-422D, R-428A, R-434A and R-507A. EPA is not aware of any significant use in the United States of the blends R-407B, R-421B, R-428A or R-434A in retail food refrigeration equipment. In addition, EPA is proposing to change the listing of HFC-227ea in new retail food refrigeration equipment from acceptable to unacceptable.³⁶ These ten refrigerants have GWPs ranging from 2,730 to 3,985. They are nonflammable. They contain compounds that are exempt from the definition of "VOC," with the exception of small amounts of R-290 and R-600a in five of the blends, and thus are not expected to contribute significantly to smog. These refrigerants are relatively low in toxicity, and practices common in the refrigeration industry ensure that their workplace exposure limits are not exceeded. These practices include adhering to those specified in the material safety data sheets and others common in the commercial refrigeration industry. Applicable workplace exposure limits for the compounds comprising these refrigerants—HFC-32, HFC-125, HFC-134a, HFC-143a, HFC-227ea, R-290 and R-600a—include Workplace

Environmental Exposure Limits (WEELs) of 1000 ppm on an 8-hour time-weighted average (TWA) from the American Industrial Hygiene Association (AIHA); a manufacturer's recommended occupational exposure limit of 1000 ppm (8-hr TWA); a permissible exposure limit (PEL) of 1000 ppm (8-hr TWA) from the Occupational Safety and Health Administration (OSHA) and a recommended exposure limit (REL) of 800 ppm (10-hr TWA) from the National Institutes for Occupational Safety and Health (NIOSH).

EPA believes there are several HFC and non-HFC substitutes that provide lower overall risk than the refrigerants EPA is proposing to list as unacceptable and that are currently used in commercial refrigeration. For both new and retrofit equipment, acceptable refrigerants that pose less risk to human health and the environment include HFC-134a, R-407A, R-407C, R-407F, R-417A, R-421A, R-422B, R-424A, R-426A, and R-438A. Additionally, in new retail food refrigeration, three other substitute refrigerants are listed as acceptable: R-717 vapor compression with secondary loop, R-410A, and R-744.

a. New Condensing Units and Supermarket Systems

EPA is proposing to change the listing of the following refrigerants from acceptable to unacceptable in new retail food refrigeration equipment (condensing units and supermarket systems) as of January 1, 2016: HFC-227ea, R-404A, R-407B, R-421B, R-422A, R-422C, R-422D, R-428A, R-434A, and R-507A. These refrigerants have GWPs ranging from approximately 2,730 to 3,985. Two of these refrigerants, R-404A and R-507A, are currently in extensive use in the retail food refrigeration market. EPA is also aware of some use of R-422A and R-422D in retrofit situations only, not in new equipment. We are not aware of the use of any of the other six refrigerants in retail food refrigeration, although we seek comment on such use.

Other acceptable alternatives that pose lower risk are also in use in the various types of retail food refrigeration equipment. For condensing unit systems, R-407C and R-407F are in use in the United States, and R-744 and HCs are being used in limited demonstration trials in Europe and elsewhere. The GWP for R-407C (a blend of HFC-32, HFC-125, and HFC-134a) is about 1,770, and R-407F (another blend of HFC-32, HFC-125, and HFC-134a) has a GWP of about 1,820. As a comparison, R-404A has a

GWP of 3,920, R-507A has a GWP of 3,990, and the other refrigerants proposed unacceptable have GWPs ranging from 2,730 to 3,985.

For multiplex rack systems, substitutes R-407A, R-407F, and R-744 are all currently in use in the United States and can be used more safely than the substances that EPA is proposing to list as unacceptable. These substitutes have GWPs ranging from 1 to 2,110. In addition, testing is underway with HCs and HFC/HFO blends, though these refrigerants have not been submitted to SNAP for review in this application. Each of these four substitutes as well as other substitutes in development with lower GWPs have zero ODP and are safe for the ozone layer. R-407A, R-407F, and R-744 all have toxicity lower than or comparable to the refrigerants proposed unacceptable. None of the three examples that would remain on the acceptable list is flammable, and none is considered a VOC.

b. Retrofit Condensing Units and Supermarket Systems

EPA is proposing to change the listing of the following refrigerants from acceptable to unacceptable in retrofit retail food refrigeration equipment (condensing units and supermarket systems) as of January 1, 2016: R-404A, R-407B, R-421B, R-422A, R-422C, R-422D, R-428A, R-434A, and R-507A. We are aware of four of these nine refrigerants being used to retrofit retail food equipment: R-404A, R-507A, R-422A, and R-422D. We are not aware of any use of the other five refrigerants to retrofit retail food refrigeration equipment but seek comment on any such use. This action would not apply to servicing existing equipment designed for these nine refrigerants or to equipment that had been retrofitted to use those refrigerants before January 1, 2016. For instance, systems retrofitted to R-404A or R-507A prior to January 1, 2016, would be allowed to continue to operate and to be serviced using those refrigerants.

For condensing units and supermarket systems, where retrofits are common, blends such as R-407A and R-407F have become the norm for retrofits, rather than the four identified in the previous paragraph. The blends R-407A and R-407F have zero ODP and GWPs of 2,107 and 1,825, respectively. Other zero-ODP refrigerants that are currently listed as acceptable for use as retrofits in retail food refrigeration include HFC-134a, R-407C, R-417A, R-421A, R-422B, R-426A and R-427A and they have GWPs ranging from 1,430 to 2,630, lower than the GWPs of the other nine blends we are proposing as

³⁶ EPA has not previously found HFC-227ea acceptable as a retrofit refrigerant in this end-use.

unacceptable, which have GWPs ranging from 2,729 to 3,985.

An unacceptability listing for these nine blends in retrofitted equipment could primarily affect the many stores that operate using HCFC-22, but also those using CFC-12, R-502, and several HCFC-containing blends such as R-401A, R-402A and R-408A. This is because as EPA reduces or eliminates the production and import of ODSs, stores will have less material to meet service demands. While the ODS phaseout does not require owners to retrofit their equipment, a decrease in the availability of virgin material may in turn lead operators of those stores to consider retrofits, although under our proposal certain refrigerants would not be acceptable. For instance, some stores currently using HCFC-22 may choose to retrofit as the production and import of HCFC-22 is phased down and eventually phased out by 2020 per 40 CFR 82.16. EPA recently proposed HCFC-22 allowance allocations for the 2014–2019 time period (December 24, 2013; 78 FR 78071). Some have questioned whether finding certain refrigerants unacceptable for retrofit might provide an incentive to stores to continue to operate with the ODS they are currently using for longer than they might otherwise plan, and we seek comment on this question. In response to this question, we note that many retail chains have been able to minimize the impact of the HCFC-22 phasedown by maintaining their own stockpile of HCFC-22, for instance by recovering from stores that are decommissioned or retrofitted and using such supplies in stores that continue to operate with HCFC-22. We also note that some service is being performed with reclaimed material, with over four million pounds of HCFC-22 being reclaimed every year since at least 2000, and over seven million pounds every year since 2006.³⁷ While we don't know how this reclaim market will change in the future, recent history shows that the market is using reclaimed material in addition to limited newly-produced supplies that are being reduced by the phaseout.

Regardless of the continued supply of HCFC-22, we believe that the majority of retrofits are planned for reasons other than the supply of the refrigerant currently in-use, for instance during planned maintenance overhauls or when upgrading to more energy efficient equipment. We also see that many retrofits are already directed towards

lower-GWP blends such as R-407A and R-407F instead of R-404A and R-507A, as mentioned above. Further, we believe that other options, given the multi-year history of their successful use, are sufficient to meet the various features—such as capacity, efficiency, materials compatibility, cost and supply—that affect the choice of a retrofit refrigerant.³⁸

3. What is EPA proposing for new and retrofit stand-alone equipment?

a. New Stand-Alone Equipment

EPA is proposing to change the listing for HFC-134a and other refrigerants for new stand-alone retail food refrigeration equipment from acceptable to unacceptable as of January 1, 2016. These other refrigerants are FOR12A, FOR12B, HFC-227ea, IKON B, KDD6, R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407A, R-407B, R-407C, R-407F, R-410A, R-410B, R-417A, R-421A, R-421B, R-422A, R-422B, R-422C, R-422D, R-424A, R-426A, R-428A, R-434A, R-437A, R-438A, R-507A, RS-24 (2002 formulation), RS-44 (2003 formulation), SP34E, and THR-03. These refrigerants have GWPs ranging from approximately 600 up to approximately 3,990.

Acceptable substitutes in new stand-alone equipment include R-744 and R-290. EPA recently proposed to find R-600a and R-441A acceptable subject to use conditions in new stand-alone equipment (July 9, 2014; 79 FR 38811). These existing and potential substitutes have GWPs ranging from 1 to 8 compared to HFC-134a with a GWP of 1,430, R-404A with a GWP of approximately 3,920, and R-507A with a GWP of approximately 3,990. None of the substitutes currently listed or proposed for listing as acceptable has an ODP. While R-290, R-600a, and R-441A are VOCs, EPA's analysis indicates that their use as refrigerants in this end-use would not significantly affect meeting national ambient air quality standards. At the time we listed R-290 as acceptable subject to use conditions, we analyzed the potential air quality impacts of emissions of these VOCs and did not find this potential risk to the environment to be significant (ICF, 2014e).³⁹ We have likewise proposed to exempt R-600a and R-441A used in stand-alone equipment from the venting prohibition (July 9, 2014; 79 FR 38811). These three substitutes are also flammable; however,

the use conditions specified (or proposed for R-600a and R-441A) would ensure that they do not pose greater risk than any of the substitutes currently listed as acceptable in new stand-alone equipment.⁴⁰ None of the refrigerants currently listed as acceptable or that we have proposed to add to the list of acceptable substitutes presents significant human health toxicity concerns or other ecosystem impacts. Apart from R-290 and R-744, those refrigerants listed acceptable for new stand-alone equipment either contain an HCFC (and are addressed in Section VI below) and/or do not appear to be in production.

We understand that R-290 is already in use globally, including in the United States, and that R-600a is in use outside of the United States as well as in test market trials in the United States. We believe that these two refrigerants can satisfy the vast majority of the current market for use in stand-alone equipment. We note that there may be a need to modify the equipment design in order to meet the use conditions for R-290 and the proposed use conditions for R-600a and R-441A (July 9, 2014; 79 FR 38811). Because there are other substitutes that pose lower risk, we are proposing to change the listing to unacceptable for new stand-alone equipment of the following refrigerants: FOR12A, FOR12B, HFC-134a, HFC-227ea, IKON B, KDD6, R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407A, R-407B, R-407C, R-407F, R-410A, R-410B, R-417A, R-421A, R-421B, R-422A, R-422B, R-422C, R-422D, R-424A, R-426A, R-428A, R-434A, R-437A, R-438A, R-507A, RS-24 (2002 formulation), RS-44 (2003 formulation), SP34E, and THR-03.

b. Retrofit Stand-Alone Equipment

EPA is proposing to change the listing for R-404A and R-507A from acceptable to unacceptable as retrofit refrigerants for stand-alone equipment as of January 1, 2016. This action would not apply to servicing existing equipment designed for those refrigerants or to equipment retrofitted to use those refrigerants before January 1, 2016. For instance, equipment retrofitted to R-404A or R-507A prior to January 1, 2016, would be allowed to continue to operate using those refrigerants.

⁴⁰ The risks due to the flammability of these refrigerants in this end-use were analyzed in the SNAP rule finding them acceptable subject to use conditions (December 20, 2011; 76 FR 78832) and docket (Docket ID No. EPA-HQ-OAR-2009-0286) and information is found in a SNAP proposed rule signed June XX, 2014 and docket (EPA-HQ-OAR-2013-0748).

³⁷ The latest data on refrigerant reclamation can be found on EPA's Web site at: www.epa.gov/spdpublic/title6/608/reclamation/recsum.pdf.

³⁸ For example, see CCAC 2012.

³⁹ EPA has proposed to exempt R-290 in stand-alone retail food refrigeration equipment from the venting prohibition found at 40 CFR 82.154 (78 FR 21871).

While we do not believe retrofits are common in stand-alone retail food refrigeration equipment, a number of refrigerants are listed as acceptable for this purpose. For equipment still operating using ozone-depleting refrigerants, we believe there are options available other than R-404A and R-507A that present lower overall risk to human health and the environment that are available. Our analysis indicates that other options such as HFC-134a can be used to retrofit stand-alone units.

4. What is EPA proposing for new and retrofit vending machines?

a. New Vending Machines

EPA is proposing to change the listing for HFC-134a and other refrigerants for new vending machines from acceptable to unacceptable as of January 1, 2016. These other refrigerants are FOR12A, FOR12B, IKON B, KDD6, R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407C, R-410A, R-410B, R-417A, R-421A, R-422B, R-422C, R-422D, R-426A, R-437A, R-438A, R-507A, RS-24 (2002 formulation), and SP34E. These refrigerants have GWPs ranging from approximately 600 up to approximately 3,990.

Acceptable existing substitutes with lower GWPs that pose less risk to human health and the environment in this end-use include R-744, which is currently being used in this end-use. In addition, EPA recently proposed to find R-600a, R-290 and R-441A acceptable subject to use conditions in new vending machines (July 9, 2014; 79 FR 38811). We note that some redesign would be required to meet the use conditions set for all three of these substitutes—R-600a, R-290 and R-441A—in the recent proposal (July 9, 2014; 79 FR 38811).

These four substitutes (R-744 and the three proposed hydrocarbons) have GWPs ranging from 1 to 8 compared to HFC-134a with a GWP of 1,430, R-404A with a GWP of approximately 3,920, and R-507A with a GWP of approximately 3,990. None of these substitutes currently listed or proposed for listing as acceptable has an ODP. While the HCs (R-441A, R-600a and R-290) are VOCs, EPA's analysis indicates that their use as refrigerants in this end-use would not significantly affect meeting national ambient air quality standards. (ICF 2014e).⁴¹ These three substitutes are also flammable; however, the proposed use conditions for these three substitutes would ensure they do

not pose greater risk than substitutes that are already listed as acceptable (July 9, 2014; 79 FR 38811). None of the substitutes currently listed or proposed to be listed as acceptable present significant human health toxicity concerns or other ecosystem impacts. Hence, we find that R-290, R-600a and R-441A are potentially available and present a lower overall risk to human health and the environment than HFC-134a and the other refrigerants proposed to be listed as unacceptable in new vending machines.

For new vending machines, EPA has found R-744 acceptable without use conditions. While the vast majority of vending machines using non-ODS refrigerant currently use HFC-134a, units are now being manufactured to use R-744. At least one major global buyer of vending machines is committed to transitioning all of their new U.S.-placed equipment to R-744.⁴² Given the large market share that this company holds, it is likely that R-744 components and units are already or will shortly become a viable option for all vending machine OEMs and purchasers.

Given the zero ODP and low GWP of R-744 and the other hydrocarbons that EPA has proposed to find acceptable subject to use conditions in vending machines, the use conditions that we have proposed to establish for the hydrocarbon refrigerants, and the fact that the risks based on other factors such as toxicity are not greater than for HFC-134a, we propose to change the listing of HFC-134a and the alternatives listed in the first paragraph of this section to unacceptable in new vending machines.

b. Retrofit Vending Machines

EPA is proposing to change the listing for R-404A and R-507A from acceptable to unacceptable as retrofit refrigerants for vending machines operating on CFC-12, HCFC-22, and blends containing HCFCs, as of January 1, 2016. This action would not apply to servicing existing equipment designed for those refrigerants or to equipment that had been retrofitted to use those refrigerants before January 1, 2016, including those systems previously using ozone-depleting refrigerants such as HCFC-22. For instance, systems retrofitted to R-404A or R-507A prior to January 1, 2016, would be allowed to continue to operate using those refrigerants.

Under our proposal, the following refrigerants would remain acceptable for retrofitting vending machines: FOR12A, FOR12B, HFC-134a, IKON A, IKON B, KDD6, R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-407C, R-417A, R-417C, R-421A, R-422B, R-422C, R-422D, R-426A, R-437A, R-438A, RS-24 (2002 formulation), SP34E, and THR-02. These refrigerants have GWPs from approximately 50 to approximately 3,100, while the two refrigerants proposed unacceptable, R-404A and R-507A, have GWPs of 3,922 and 3,985, respectively. In this respect, these two refrigerants present a higher risk to human health and the environment. Looking at the other SNAP criteria, we find that those refrigerants remaining acceptable present similar risk to human health and the environment: they are nonflammable, they are not VOCs, and they do not exhibit significant human health toxicity concerns or other ecosystem impacts. Hence, we believe these options present lower overall risk to human health and the environment than R-404A and R-507A.

5. When would the listings change?

Through this action, we are proposing that all listing changes that apply within commercial refrigeration would occur on the same date—January 1, 2016. Looking at the intersection between the end-use and the alternatives EPA believes that changing the listings as of January 1, 2016, allows sufficient opportunity for any planned new installations or manufacturing equipment lines in these end-uses to be redesigned to use a substitute to the refrigerants we are proposing to find unacceptable. We also believe that this date would allow any plans for future retrofits to these blends to be reconsidered, given the multiple other substitutes that would remain acceptable. For many years other refrigerants such as R-407A and R-407F that would remain on the acceptable lists pursuant to our proposal have been gaining market share in supermarket applications, in both new equipment and as retrofit fluids.⁴³ As part of this market expansion, manufacturers have developed equipment to use them, and that equipment is available to buyers now. In addition, many companies have implemented these other refrigerants, in both new construction and as retrofits, and have built up the skills, knowledge and experience to more fully utilize these refrigerants in a timeframe that would accommodate January 1, 2016 as

⁴¹ EPA has proposed to exempt R-290 (propane) R-600a (isobutane) and R-441A in vending machines from the venting prohibition found at 40 CFR 82.154 (78 FR 21871).

⁴² The Coca-Cola Company has identified carbon dioxide as its HFC-free refrigerant of choice for new equipment (Coca Cola, 2012).

⁴³ ICF, 2014c. Market Characterization of the U.S. Commercial Refrigeration Industry. Prepared for the U.S. Environmental Protection Agency. May, 2014.

the date of unacceptability. For stand-alone equipment and vending machines, new equipment is being installed using refrigerants that are acceptable or are proposed acceptable with use conditions, including R-744, R-290 and R-600a.⁴⁴ EPA requests comment on this proposed date. EPA is also interested in information concerning the supply of substitutes in sufficient quantities to meet a domestic transition within the proposed timeframe.

6. Applicability To Service of Existing Equipment

As noted above, EPA is not proposing to alter the ability to service existing retail food refrigeration equipment or vending machines with the refrigerant they contain as of January 1, 2016. We recognize the value of the currently installed appliances and are not seeking to shorten their useful lifetime. EPA also recognizes that servicing for existing equipment is often accomplished with recovered and recycled refrigerants.

EPA seeks comments on allowing for the continued servicing of the existing retail food refrigeration equipment and vending machines with the refrigerant they contain as of January 1, 2016.

7. Energy Efficiency Consideration

Energy efficiency has not historically been a criterion by which a refrigerant is analyzed under the SNAP program, and it is not used as one of the criteria in this proposal. However, EPA recognizes that the energy efficiency of particular models of equipment is a significant factor when choosing commercial refrigeration equipment. We also recognize that the energy efficiency of any given piece of equipment is in part affected by the choice of refrigerant and the particular thermodynamic and thermophysical properties that refrigerant possesses.

Throughout the phaseout of ozone-depleting substances, EPA has seen the energy efficiency of refrigeration and air-conditioning equipment increase, despite changing refrigerant options. In some cases, this was because new chemicals were developed that possessed unique properties that allowed high energy efficiency levels to be obtained. In addition, technological improvement in equipment designs and controls has increased energy efficiency. Although today's proposal would eliminate some refrigerant choices, we do not believe it would have a detrimental effect on this trend in increased energy efficiency. In fact, there are multiple case studies available that highlight the energy efficiency

gains achieved by some of the low-GWP refrigerants, such as R-744, R-290 and R-600a, that are available or potentially available for the end-uses addressed in this proposal. We welcome additional information and comment on improved energy efficiency associated with switching refrigerants.

For instance, in supermarket refrigeration, a theoretical analysis (Emerson 2014) examined the energy use of R-407A and R-410A, both of which would remain acceptable under this proposal, against that of R-404A, which would be listed as unacceptable. Although this analysis found that both blends would see a 3.6% to 6.7% drop in efficiency in the low-temperature part of the store (e.g., frozen food, ice cream), they would achieve a 4.3% to 13.3% increase in the medium-temperature part of the store (e.g., meat, dairy products, chilled prepared food). Given that supermarkets have significantly larger use of medium-temperature equipment, the net effect would be for the alternatives to use less energy than R-404A. This manufacturer's analyses showed similar increases in energy efficiency compared to R-404A in supermarkets and stand-alone equipment for a variety of low-GWP refrigerants that are not yet listed under SNAP but are in development.

While that manufacturer's analysis showed slightly higher energy consumption than R-134a in theoretical calculations for stand-alone equipment, other results with actual equipment have shown otherwise. For instance, in stand-alone equipment, one user reported that "HC freezers are significantly more energy-efficient and use a natural hydrocarbon refrigerant with lower global warming potential than the HFC refrigerants commonly used in US freezers" (Ben and Jerry's, 2014). Likewise, for vending machines, one purchaser has indicated that while introducing over one million units using R-744, they have increased the energy efficiency of their cooling equipment over 40% since 2000, many years after they adopted HFC-134a (Coca-Cola, 2014).

Finally, we note that energy efficiency is influenced, but not determined, by the refrigerant. As new products are designed for the use of particular refrigerants, manufacturers have the opportunity to change designs to take advantage of a given refrigerant's characteristics. The redesign and development phase is also an opportunity to improve other components that will affect the overall efficiency of the equipment, such as the use of more efficient motors and compressors, improved heat exchangers,

better controls, improved insulation (e.g., on display cases) and sealing (for products with doors), more efficient lighting, etc.

The United States Department of Energy (DOE) has promulgated, under separate rulemaking and separate authority, energy efficiency requirements for several types of commercial refrigeration equipment, including products that would be affected by this proposal. While EPA's proposal would limit the choice of refrigerant a manufacturer could use in new equipment, EPA notes that such equipment would still be subject to the DOE requirements and would normally need to meet the standards set.⁴⁵ As discussed above, EPA does not believe this proposal would prevent compliance with the DOE rules, and we note that many compliant models are already commercially available that do not use the refrigerants EPA has proposed as unacceptable. EPA requests comment on the effects this proposal would have on the energy efficiency of the commercial refrigeration end-uses addressed and in particular the effect, if any, this proposal would have on meeting applicable DOE standards.

8. What other options is EPA considering?

EPA is considering but is not proposing to change the listing for several other substitutes in retail food refrigeration. We are seeking comment on these substitutes.

a. New and Retrofit Condensing Units and Supermarket Systems

When analyzing supermarket retail food refrigeration systems, as an alternative to changing the listing to unacceptable for HFC-227ea, R-407B, R-421B, R-422A, R-422C, R-422D, R-428A, and R-434A, we are considering setting a use restriction to limit the charge size of these chemicals allowed to be used in condensing units and supermarket systems. Supermarkets could use systems employing one of the

⁴⁵ Refrigeration equipment in the applicable covered equipment class would still be subject to DOE's standards, regardless of the refrigerant that the equipment uses. If a manufacturer believes that its design is subjected to undue hardship by a regulatory standard prescribed by DOE (in contrast to one that is statutorily prescribed by Congress), the manufacturer may petition DOE's Office of Hearing and Appeals (OHA) for exception relief or exemption from the standard pursuant to OHA's authority under section 504 of the DOE Organization Act (42 U.S.C. 7194), as implemented at subpart B of 10 CFR part 1003. OHA has the authority to grant regulatory relief from a standard promulgated by DOE on a case-by-case basis if it determines that a manufacturer has demonstrated that meeting the standard would cause hardship, inequity, or unfair distribution of burdens.

⁴⁴ *Ibid.*

many advanced refrigeration designs currently deployed in the United States, such as distributed refrigeration, secondary-loop, and cascade designs. To set the charge size limit, EPA is considering the charge size limit that is necessary, but not fully sufficient, to achieve a Gold-Level Store Certification under EPA's GreenChill Store Certification Program.⁴⁶ That specification requires that the store must achieve an average HFC refrigerant charge equal to or less than 1.25 pounds of refrigerant per MBTU/hr total evaporator heat load.⁴⁷

For new equipment, one reason we are considering a use restriction requiring a small charge is to limit the amount of high-GWP refrigerant that would be emitted in a catastrophic event. However, given the high GWP of these refrigerants compared to other refrigerants that are available in these end-uses, we do not believe that use with a small charge size adequately addresses the greater risk they pose. Further, we recognize that using a lower-GWP refrigerant, such as R-407A or R-407F, is also possible in small-charge systems, and several stores are operating with such systems today.

For retrofits, two primary factors lead us to consider a use restriction for a small charge size in place of listing the substitutes as unacceptable. First, there are many different supermarket systems in operation with ozone-depleting refrigerants today, and there may be some concern that not all could be retrofitted with the lower-GWP blends, i.e., whether there truly are alternatives "available" for the purpose. As to this concern, we reflect on three points. First, based on the regulations phasing out CFCs in 1996, equipment using CFCs today would be at least 18 years old, beyond the typical average lifetime.⁴⁸ Because it is typical to retire older equipment before newer equipment, it is likely that many stores using those refrigerants would be decommissioned, or the refrigeration systems would be replaced rather than retrofitted. Second, we do not see an impediment in the continued operation of stores currently using refrigerants proposed unacceptable for new and/or retrofit equipment (see section 6 above). We know that some stores have systems

that continue to use CFC-12 and/or R-502, the production and import of which was phased out in 1996, and believe the same long equipment lifetimes can be achieved, if desired, with equipment installed prior to January 1, 2016, using the refrigerants we propose as unacceptable. Finally, where retrofits to refrigerants that are not proposed as unacceptable have occurred, the industry has been able to achieve acceptable capacity and efficiency levels. All these factors point to the ability of industry to make business decisions on which stores to decommission or retrofit and when to do so while maintaining their operations without the need to rely on the refrigerants we are proposing as unacceptable.

Second, some have questioned whether removing options from the list of acceptable retrofit substitutes might present a perverse incentive for stores with older systems (more likely to leak) to continue use of ozone-depleting refrigerants, primarily HCFC-22 but also CFC-12, R-502, and multiple blends containing HCFCs, rather than retrofit or replace those systems with a new refrigerant. While production and import of HCFC-22 and all other HCFCs used in the acceptable retrofit blends are capped, the stores using them would continue to leak ozone-depleting refrigerants into the atmosphere. The additional refrigerant that they would need to service that leaky equipment might not have been produced in the first place if the demand was not there. Nonetheless, given the tight controls on production and import of ozone-depleting refrigerants, we believe the market will determine where those limited supplies are directed and where a store may retrofit to a refrigerant other than those proposed to be listed as unacceptable.

EPA requests comments on both concerns addressed above, particularly the availability of substitutes able to work with the design of existing systems that might be retrofitted, and the possible perverse incentives an unacceptable listing might bring to continue to operate older, less efficient, and/or leakier ODS systems. EPA also requests comments on the specified charge size limit and how it would be met in both new and retrofit retail food refrigeration (condensing units and supermarket systems) if EPA were to propose a use restriction rather than take final action by listing some or all of these refrigerants as unacceptable for condensing units and supermarket systems.

b. New Stand-Alone Equipment and Vending Machines

For new stand-alone retail food refrigeration equipment and vending machines, we are considering maintaining the acceptability status of HFC-134a and blends with a lower GWP—FOR12A, FOR12B, IKON A, IKON B, SP34E, THR-02, and THR-03—subject to a use restriction. One reason to maintain the acceptability of these refrigerants, in particular HFC-134a, would be to allow niche applications to continue to use the primary refrigerant employed in these end-uses while new low-GWP substitutes are developed.

For new vending machines, we are considering whether substitutes other than HFC-134a are available for low-temperature refrigeration applications, for instance, for ice-cream novelty or microwavable frozen-food vending machines and, if not, whether to establish a use restriction that HFC-134a could only be used in vending machines designed for, and maintaining, an internal temperature of 32 °F (0 °C) or below. However, we believe that the availability of R-744, which is listed as acceptable, and the availability of HCs, which we have proposed to list as acceptable, do not support such an action. We are requesting comment on the viability of these substitutes in low-temperature applications. Further, we are asking for comment on the supply of components designed for R-744, hydrocarbons, or other potential substitutes for use in low-temperature vending machines and how that supply might affect the ability of manufacturers to continue to provide such equipment to meet these applications and customers' requirements including energy efficiency goals.

For new stand-alone equipment, we note that HCs pose additional challenges related to their flammability. Some stand-alone retail food refrigeration appliances utilizing HCs have required design changes, and our use conditions require meeting specific charge size limits, raising questions of the viability of HCs in all larger applications within this end-use. EPA is considering adding a use restriction limiting the use of HFC-134a and the blends mentioned to only larger-sized units, while finding it unacceptable in smaller-sized units. To determine the dividing line between "small" and "large" units, we are considering options such as the number of doors within a single unit, the refrigeration capacity of the unit, and the interior volume.

⁴⁶ Additional information on GreenChill is available at <http://www2.epa.gov/greenchill/>.

⁴⁷ In addition to reaching this HFC charge size limit, stores must use only non-ozone-depleting refrigerants and must meet a store-wide annual refrigerant emissions rate of no more than 15% in order to be certified at the Gold level.

⁴⁸ For example, IPCC 2006 indicates that the average lifetime of medium and large commercial refrigeration equipment is between seven and 15 years.

Although we are considering this option, we are not proposing it because we feel other options exist to design units using other less harmful alternatives, even in large stand-alone units. The SNAP acceptability listing for R-744 in stand-alone equipment does not include a restriction on charge size or any other use condition. We also recognize the ability to apply separate refrigeration circuits within a given cabinet; for instance one circuit with up to 150 grams of R-290 to cool a portion of the unit and a second circuit with up to 150 grams of R-290 to cool the rest of the unit. Such dual-circuit designs might be particularly effective if different parts of the unit are used for different products that require different temperature conditions or have different refrigeration loads.

EPA seeks comments on this option and particularly on how one would determine what size of a unit could not use substitutes that would remain on the acceptable list under this proposal or that we have recently proposed be added to the acceptable list; where the dividing line would be drawn; and how such a use restriction could avoid unintended consequences such as the over-sizing of units to allow the use of HFC-134a.

EPA believes that R-744, an acceptable option for both new stand-alone retail food refrigeration equipment and new vending machines, and R-290, an acceptable substitute for new stand-alone retail food refrigeration equipment and proposed as acceptable for new vending machines, could satisfy the vast majority of new equipment in these end-uses. However, we seek additional information and studies that would help us understand whether certain designs (e.g., 3-door and other large retail food refrigeration stand-alone equipment) could meet the charge size limit in the case of R-290. We also seek information regarding whether certain applications (e.g., low-temperature vending machines) could be effective while maintaining current energy efficiency levels in the case of R-744.

c. Retrofit Stand-Alone Equipment and Vending Machines

EPA has proposed to find R-404A and R-507A unacceptable for retrofits in both stand-alone equipment and vending machines. EPA is considering also changing the acceptability status of several other refrigerants to unacceptable. Under this option, we would change the status of the following refrigerants from acceptable to unacceptable in retrofit retail food refrigeration (stand-alone equipment): KDD6, R-125/290/134a/600a (55.0/1.0/

42.5/1.5), R-404A, R-407A, R-407B, R-407C, R-407F, R-417A, R-417C, R-421A, R-421B, R-422A, R-422B, R-422C, R-422D, R-424A, R-426A, R-427A, R-428A, R-434A, R-437A, R-438A, R-507A, RS-24 (2002 formulation), and RS-44 (2003 formulation). Likewise, this option would change the status of the following refrigerants from acceptable to unacceptable in retrofit vending machines: KDD6, R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407C, R-417A, R-417C, R-421A, R-422B, R-422C, R-422D, R-426A, R-437A, R-438A, R-507A, and RS-24 (2002 formulation). The refrigerants in these two lists have GWPs that range from 1,505 to 3,985.

These refrigerants have higher GWPs than HFC-134a, which would remain acceptable for retrofits, and in this respect pose a higher risk to human health and the environment. Similar to HFC-134a, these other refrigerants do not pose increased risk due to toxicity, flammability, ODP and ecological effects. EPA believes that HFC-134a would be the most likely refrigerant to be used to retrofit stand-alone equipment and vending machines still operating on ozone-depleting refrigerant. EPA questions whether the other refrigerants listed above would serve any retrofit need, and whether finding them unacceptable would reduce overall risk to human health and the environment. EPA believes some existing vending machines and stand-alone equipment still use class I ozone-depleting refrigerants such as CFC-12 and R-502 and that even more equipment continues to use class II ozone-depleting refrigerants, primarily HCFC-22. Other than HFC-134a, we do not believe there are substitutes that would likely be used for most of this equipment for purposes of retrofitting.

We seek comment on the option of finding other substitutes, in addition to R-404A and R-507A, unacceptable as retrofit refrigerants in vending machines and stand-alone retail food refrigeration equipment. In particular, we are interested in an assessment of the existing stock of equipment operating with ozone-depleting refrigerants, the likelihood that they will require a retrofit before being replaced with a new unit, and the substitute(s) that could be and are likely to be used.

d. Status of R-404A and R-507A in Other End-Uses

Considering the high GWP of R-404A, R-507A, and some of the other blends proposed as unacceptable, EPA is considering finding them unacceptable in several other end-uses, besides retail

food refrigeration and vending machines, such as cold storage rooms and warehouses, ice machines, refrigerated transport, and industrial process refrigeration. We believe that the substitutes that are being used in retail food refrigeration, such as R-407A and R-407F, would be theoretically viable in these other end-uses too, given that the operational characteristics of such equipment, such as temperature to be maintained, are similar. Those two substitutes, and others, have been found acceptable in the four end-uses mentioned. In addition, low-GWP substitutes have been found acceptable under SNAP for some of these end-uses, and research is underway in the others. For example, for the industrial process refrigeration end-use, R-744, R-717, and several HCs have been found acceptable. For cold storage warehouses, R-744 is acceptable for new equipment, and R-717 is in widespread use. R-744 for refrigerated transport and HCs for ice machines have been tested and, although not yet listed under SNAP, are being used outside the United States. In these two end-uses, the list of acceptable refrigerants is similar to that for supermarket applications, spanning a wide range of GWPs. Several HFC blends with GWPs considerably lower than those of R-404A and R-507A are being used in retail food refrigeration, especially in supermarkets and, as stated above, are acceptable in the four end-uses mentioned; however, we have limited knowledge of their use in these other end-uses. For that reason, we have not proposed finding R-404A and R-507A unacceptable in these other end-uses.

EPA requests comment on the use and viability of both low-GWP refrigerants (e.g., R-744, R-717, and HCs) and other HFC-blends (e.g., R-407A and R-407F) and the possibility of listing R-404A, R-507A, and other high-GWP blends unacceptable in any or all of these four end-uses—cold storage warehouses, ice machines, refrigerated transport, and industrial process refrigeration. EPA also solicits comments on the feasibility of the proposed deadlines and whether earlier or later dates would be more appropriate.

D. Foam Blowing Agents

EPA is proposing to change the listings from acceptable to unacceptable beginning January 1, 2017, except where allowed under a narrowed use limit, for HFC-134a and blends thereof in all foam blowing end-uses, and for HFC-365mfc, HFC-245fa and blends thereof for all foam blowing end-uses except spray foam applications. Specific end-uses and applications include: (1) Rigid

polyurethane appliance foam; (2) flexible polyurethane; (3) rigid polyurethane: commercial refrigeration, and sandwich panels; (4) rigid polyurethane (slabstock and other); (5) rigid polyurethane and polyisocyanurate laminated boardstock; (6) integral skin polyurethane; (7) polystyrene (extruded sheet); (8) polystyrene: extruded boardstock and billet; (9) polyolefin; and (10) phenolic insulation board and bunstock. In addition, EPA is proposing to change the listings from acceptable to unacceptable for the following foam blowing agents in the following end-uses as of January 1, 2017: (1) Formacel B in polystyrene (extruded boardstock and billet); (2) Formacel TI in rigid polyurethane appliance foam, rigid polyurethane (spray, commercial refrigeration, and sandwich panels), rigid polyurethane slabstock, integral skin polyurethane, polystyrene extruded sheet and polyolefin; (3) Formacel Z-6 in rigid polyurethane appliance foam, rigid polyurethane (commercial refrigeration, and sandwich panels), rigid polyurethane slabstock, polystyrene (extruded boardstock and billet), integral skin polyurethane, and polystyrene extruded sheet; and (4) HFC-143a in phenolic insulation board and bunstock.

1. Background

Foams are plastics (such as polyurethane or polystyrene) that are manufactured using blowing agents to create bubbles or cells in the material's structure. The foam plastics manufacturing industries, the markets they serve and the blowing agents used are extremely varied. The range of uses includes building materials, appliance insulation, cushioning, furniture, packaging materials, containers, flotation devices, filler, sound proofing and shoe soles. Some foams are rigid with cells that still contain the foam blowing agent, which can contribute to the foam's ability to insulate. Other foams are open-celled, with the foam blowing agent escaping at the time the foam is blown, as for flexible foams.

Historically, a variety of foam blowing agents have been used for these applications. CFCs and HCFCs were typically used given their favorable chemical properties. CFCs and HCFCs are controlled substances under the Montreal Protocol and subject to regulation under the CAA including a phaseout of production and import under section 604 for CFCs and section 605(b)-(c) for HCFCs and use restrictions on HCFCs under section 605(a). The regulations implementing section 610 of the CAA include a ban on

sale or distribution of foam products blown with class I and class II ODS: however, for foam products containing a class II ODS, the ban is subject to an exception for foam insulation products as defined at 40 CFR 82.62.

The SNAP program has found acceptable a variety of non-ODS blowing agents, including HFCs (e.g., HFC-134a, HFC-245fa, HFC-365mfc), hydrocarbons, carbon dioxide, water, and methyl formate. In addition, low-GWP fluorinated compounds in use include HFO-1234ze(E) and *trans*-1-chloro-3,3,3-trifluoroprop-1-ene (Solstice 1233zd(E)).

Blowing agents are approved on an end-use basis. The SNAP program considers the following end-uses:

- a. Rigid polyurethane (appliance foam) includes insulation foam in domestic refrigerators and freezers.
- b. Rigid polyurethane (spray, commercial refrigeration, and sandwich panels) includes buoyancy foams, insulation for roofing, wall, pipes, metal doors, vending machines, coolers, and refrigerated transport vehicles.
- c. Rigid polyurethane (slabstock and other) includes insulation for panels and pipes.
- d. Rigid polyurethane and polyisocyanurate laminated boardstock includes insulation for roofing and walls.
- e. Flexible polyurethane includes foam in furniture, bedding, chair cushions, and shoe soles.
- f. Integral skin polyurethane includes car steering wheels, dashboards, and shoe soles.
- g. Polystyrene (extruded sheet) includes foam for packaging and buoyancy or flotation.
- h. Polystyrene (extruded boardstock and billet) includes insulation for roofing, walls, floors, and pipes.
- i. Polyolefin includes foam sheets and tubes.
- j. Phenolic insulation board and bunstock includes insulation for roofing and walls.

2. What is EPA proposing for foam blowing agents?

EPA is proposing to change the listings from acceptable to unacceptable for HFC-134a, HFC-245fa, HFC-365mfc, and any blends containing these blowing agents for all foam end-uses and applications except for spray foam as of January 1, 2017. In addition, we propose to change the listings from acceptable to unacceptable for the following foam blowing agents in the following end-uses: (1) Formacel B in polystyrene (extruded boardstock and billet); (2) Formacel TI in rigid polyurethane appliance foam, rigid

polyurethane (spray, commercial refrigeration, and sandwich panels), rigid polyurethane slabstock, integral skin polyurethane, polystyrene extruded sheet and polyolefin; (3) Formacel Z-6 in rigid polyurethane appliance foam, rigid polyurethane (commercial refrigeration, and sandwich panels), rigid polyurethane slabstock, polystyrene (extruded boardstock and billet), integral skin polyurethane, and polystyrene extruded sheet; and (4) HFC-143a in phenolic insulation board and bunstock, all as of January 1, 2017—that is, it would be prohibited to blow foam using these blowing agents for these uses beginning January 1, 2017. In addition, we propose that it would be prohibited to import closed cell foam products or products containing closed cell foam that contain any of the blowing agents listed as unacceptable. EPA is also seeking comment on whether the Agency should consider use of the foam blowing agent to apply to open cell foam and products containing open cell foam, and in particular what would be the legal basis for doing so. Finally, we are providing a limited exception to the date when the unacceptability determinations apply for certain military and space applications where there is documentation that additional time is required to complete qualification testing.

a. What other foam blowing agents are being used?

Various foam blowing agents have been historically used. The opportunity to use hydrocarbons (HCs), CO₂, and water in the 1990s for a range of foam blowing applications in the United States has allowed many foam blowing end-uses and applications to transition from ODS, thus reducing the end-uses that rely on HCFCs or HFCs. HCs have been a low-GWP and cost-effective alternative available for large parts of the foam sector, particularly in flexible polyurethane foam, polystyrene sheet foam, polyurethane slabstock foam, polyurethane and polyisocyanurate laminated boardstock, phenolic, and polyolefin foams. HCs also are used in most of the other end-uses, but less extensively than in these six end-uses. However, flammability of foam blowing agents, including HCs, can be a concern, particularly for spray foam applications.

Over the past ten years both fluorinated and non-fluorinated alternatives have expanded both the list of options for specific foam uses and the foam uses in which these alternatives are now used has also grown. A number of new foam blowing agents with low GWPs have been introduced during the

past several years. Many end users have indicated interest in these newer alternatives, often to improve energy efficiency of the foam products manufactured with the foam blowing agent. Production volumes for some of these newer substitutes are expanding rapidly to keep pace with growing demand. For example, HFO-1234ze(E) and *trans*-1-chloro-3,3,3-trifluoroprop-1-ene have recently been listed as acceptable. HFO-1336mzz(Z) is currently under review by EPA as a substitute foam blowing agent. These newer substitutes, which do not raise the flammability concerns of HCs, may prove appropriate for end-uses where flammable agents raise safety concerns. The process and timing for retooling facilities that use the blowing agents or that incorporate the foam product into another product will vary depending on the substitute selected. In some cases, manufacturing facilities such as household refrigerator manufacturers have already begun the testing of and transitioning to lower-GWP substitutes for foam blowing.

b. What are the health and environmental impacts of the substitute foam blowing agents?

i. Proposed Unacceptable Agents

The HFCs that we are proposing to find unacceptable have GWPs ranging from 794 for HFC-365mfc to 4470 for HFC-143a, which is significantly higher than the GWPs of other acceptable substitutes. The HFC blends that we are proposing to find unacceptable have GWPs that vary depending on the specific composition; the range of GWPs for blends are 140 to 1500 for Formacel B, 1330 to close to 1500 for Formacel TI, 370 to 1290 for Formacel Z-6, 740 to 1030 for blends of HFC-365mfc with at least 4% HFC-245fa, and 900 to 1100 for commercial blends of HFC-365mfc with 7 to 13% HFC-227ea and the remainder HFC-365mfc. All of the HFCs and HFC blends that we are proposing to find unacceptable consist of compounds that are non-ozone-depleting and are VOC-exempt. Toxicity is not a significant concern for these alternatives because they may be used for blowing foam consistent with required or recommended workplace exposure limits. For example, HFC-134a, HFC-143a, and HFC-245fa can be used consistent with their respective AIHA WEELs of 1000 ppm, 1000 ppm, and 200 ppm (8-hr TWA) in the foam end-uses where they are acceptable. Of the foam blowing agents that we propose to be unacceptable, some are nonflammable (HFC-134a, HFC-245fa, Formacel TI, blends of HFC-365mfc

with at least 4% HFC-245fa, and commercial blends of HFC-365mfc with 7 to 13% HFC-227ea and the remainder HFC-365mfc), while others are flammable (HFC-365mfc and HFC-143a). The HFC blends Formacel B and Formacel Z-6 may be flammable depending on the exact composition, with the less flammable or nonflammable formulations having higher GWPs, in some cases as high as 1300 to 1500.

In addition to the GWP of foam blowing agents, another potential climate impact from foam blowing agents is the insulation value of the blown foam. This may matter for rigid insulation foams, where the foam blowing agent may add more or less insulation value to rigid polyurethane appliance foam; rigid polyurethane spray, commercial refrigeration and sandwich panels; rigid polyurethane slabstock and other foam; polystyrene extruded boardstock and billet; rigid polyurethane and polyisocyanurate laminated boardstock; and phenolic insulation board and bunstock. A foam with better overall insulation value can reduce indirect greenhouse gas emissions from power plants if the foam insulation results in greater energy efficiency and less need for heating or cooling. Some studies have indicated that hydrocarbons and CO₂ may provide less insulation value to an insulation foam, pound for pound, than HFCs. Recent information on some of the newer fluorinated foam blowing agents with low GWPs, such as HFO-1234ze(E) and *trans*-1-chloro-3,3,3-trifluoroprop-1-ene, indicates these foam blowing agents provide comparable or greater insulation value than their HCFC and HFC predecessors and therefore may be of interest to companies considering transition to more energy-efficient options. In addition, even a foam blowing agent that provides less insulation value may still not impact the foam's overall energy efficiency where thicker foam is used. Because of the variety of foam blowing agents available in each end-use, we believe that there are sufficient options that will not have an adverse impact on indirect greenhouse emissions.

ii. Rigid Polyurethane Appliance Foam

For rigid polyurethane appliance foam, saturated light HCs (C3-C6⁴⁹), CO₂, vacuum panels, water, ecomate™, Exxsol blowing agents, methyl formate, HFO-1234ze(E), and *trans*-1-chloro-3,3,3-trifluoroprop-1-ene are acceptable

⁴⁹ These are hydrocarbons with three to six carbons, including propane, butane, isobutane, pentane, isopentane, cyclopentane, and hexane.

alternatives (in-kind and not-in-kind) with GWPs that range from zero to seven. Toxicity is not a significant concern for these alternatives because they may be used for blowing appliance foam consistent with required or recommended workplace exposure limits. With the exception of HCs and Exxsol blowing agents, these alternatives contain compounds that are exempt from the definition of VOC. Of the alternatives listed above, only *trans*-1-chloro-3,3,3-trifluoroprop-1-ene contains chlorine and has measurable ODP. Its ODP of 0.00024 to 0.00034^{50 51} is roughly one order of magnitude higher than the ODP of HFC-134a which is considered to have zero ODP.⁵² *Trans*-1-chloro-3,3,3-trifluoroprop-1-ene's impact on global atmospheric ozone abundance is expected to be statistically insignificant.⁵³ Of the various options listed in this paragraph, ecomate™, Exxsol blowing agents, HCs, and methyl formate are flammable, and the others are nonflammable. The hazards of the flammable compounds in this end-use can be adequately addressed in the process of meeting OSHA regulations and fire codes. In this end-use, HFC-134a, Formacel TI, HFC-245fa, HFC-365mfc, and Formacel Z-6 have significantly higher GWPs than the other available substitutes mentioned above in this paragraph, thereby increasing overall risks to human health and the environment.

iii. Flexible Polyurethane

For flexible polyurethane used for foam furniture, bedding, chair cushions, shoe soles and other applications, acceptable substitutes include acetone, saturated light HCs (C3-C6), Exxsol blowing agents, CO₂, ecomate™ (i.e., methyl formate), HFC-152a, and water with GWPs ranging from zero to 124. Of the substitutes listed for flexible polyurethane, all have an ODP of zero. Toxicity is not a significant concern for these substitutes because they may be used for blowing flexible polyurethane foam consistent with required or recommended workplace exposure limits. With the exception of HCs and Exxsol blowing agents, these substitutes contain compounds that are exempt

⁵⁰ Wang D., Olsen S., Wuebbles D. 2011. "Preliminary Report: Analyses of tCFP's Potential Impact on Atmospheric Ozone." Department of Atmospheric Sciences. University of Illinois, Urbana, IL. September 26, 2011.

⁵¹ Patten and Wuebbles, 2010. "Atmospheric Lifetimes and Ozone Depletion Potentials of *trans*-1-chloro-3,3,3-trichloropropylene and *trans*-1,2-dichloroethylene in a three-dimensional model." *Atmos. Chem. Phys.*, 10, 10867-10874, 2010.

⁵² Wang et al., 2011. *Op. cit.*

⁵³ Wang et al., 2011. *Op. cit.*

from the definition of VOC. Of the various options listed in this paragraph, ecomate™, Exxsol blowing agents, HFC–152a, and hydrocarbons are flammable, and the others are nonflammable. The flammability hazards of the flammable compounds in this end-use can be adequately addressed in the process of meeting OSHA regulations and fire codes. In this end-use, HFC–134a, HFC–245fa, and HFC–365mfc have significantly higher GWPs than the other available substitutes mentioned above in this paragraph, thereby increasing overall risks to human health and the environment.

iv. Rigid Polyurethane Spray Foam

For rigid polyurethane spray foam, which includes insulation for roofing, wall, pipes, and buoyancy, acceptable substitutes include HFC–245fa, commercial blends of HFC–365mfc and HFC–227ea, containing 7% to 13% HFC–227ea and the remainder HFC–365mfc, blends of HFC–365mfc and at least 5% HFC–245fa, CO₂, water, Exxsol blowing agents, ecomate™, HFO–1234ze(E), and *trans*-1-chloro-3,3,3-trifluoroprop-1-ene, with GWPs ranging from zero to 1100. Toxicity is not a significant concern for these alternatives because they may be used for spray foam consistent with required or recommended workplace exposure limits. With the exception of Exxsol blowing agents, these substitutes contain compounds that are exempt from the definition of VOC. Of the substitutes listed above, only *trans*-1-chloro-3,3,3-trifluoroprop-1-ene has an ODP, and as discussed above for rigid polyurethane appliance foam, its impact on global atmospheric ozone abundance is expected to be statistically insignificant.

Flammability is of particular concern in spray foam applications, in part because they are applied onsite in pressurized equipment with spray guns, sometimes in proximity to hot, flammable substances such as tar. The alternative manufacturers have developed training to assist end-users in addressing the flammability hazards of the flammable compounds in this end-use (Exxsol blowing agents and ecomate™); however, these alternatives have limited, if any, use in spray foams in the United States.^{54 55} Flammability

risks are more difficult to mitigate than in most other foam applications because, unlike in a factory setting, it is unlikely that ventilation can be provided that removes flammable vapors and maintains them below the lower flammability limit, and it is not practical to make all electrical fixtures explosion proof when applying spray foam in place in a residential building. Thus, EPA is proposing to find HFC–134a and blends thereof and Formacel TI unacceptable in this application. We are proposing that HFC–245fa; commercial blends of HFC–365mfc and HFC–227ea, containing 7% to 13% HFC–227ea and the remainder HFC–365mfc; and blends of HFC–365mfc and at least 5% HFC–245fa remain acceptable in spray foam because these three nonflammable foam blowing agents reduce overall risk compared to the available flammable alternatives. The three HFC blends that remain acceptable reduce overall risks to human health and the environment compared to HFC–134a and Formacel TI in this application because they have lower GWPs.

v. Rigid Polyurethane Used in Commercial Refrigeration and Sandwich Panels

For rigid polyurethane used in commercial refrigeration and sandwich panels, which includes insulation for roofing, wall, metal doors, vending machines, coolers, buoyancy, and refrigerated transport vehicles, acceptable alternatives include saturated light HCs (C3–C6), ecomate™, CO₂, water, Exxsol blowing agents, methyl formate, HFO–1234ze(E), and *trans*-1-chloro-3,3,3-trifluoroprop-1-ene with GWPs ranging from zero to seven. Toxicity is not a significant concern for these alternatives because they may be used for blowing foam for commercial refrigeration and sandwich panels, consistent with required or recommended workplace exposure limits. With the exception of hydrocarbon, and Exxsol blowing agents, these substitutes contain compounds that are exempt from the definition of VOC. Of the substitutes listed above, only *trans*-1-chloro-3,3,3-trifluoroprop-1-ene has an ODP and as discussed above for rigid polyurethane appliance foam, its impact on global atmospheric ozone abundance is expected to be statistically insignificant. Of the various substitutes listed in this paragraph, ecomate™, Exxsol blowing agents, formic acid, hydrocarbons, and methyl formate are flammable, and the others are nonflammable. The flammability hazards of the flammable compounds in this end-use can be

adequately addressed in the process of meeting OSHA regulations and fire codes. In these applications, HFC–134a, HFC–245fa, HFC–365mfc, Formacel Z–6 and Formacel B have significantly higher GWPs than the other available substitutes mentioned above in this paragraph, thereby increasing overall risks to human health and the environment.

vi. Rigid Polyurethane Slabstock and Other Foam

For rigid polyurethane slabstock and other foam, saturated light HCs (C3–C6), CO₂, water, ecomate™, Exxsol blowing agents, methyl formate, HFO–1234ze(E), and *trans*-1-chloro-3,3,3-trifluoroprop-1-ene are acceptable alternatives with GWPs that range from zero to seven. Toxicity is not a significant concern for these alternatives because they may be used for blowing slabstock foam consistent with required or recommended workplace exposure limits. With the exception of HCs and Exxsol blowing agents, these alternatives contain compounds that are exempt from the definition of VOC. Of the alternatives listed above, only *trans*-1-chloro-3,3,3-trifluoroprop-1-ene has an ODP, and as discussed above for rigid polyurethane appliance foam, its impact on global atmospheric ozone abundance is expected to be statistically insignificant. Of the various options listed in this paragraph, ecomate™, Exxsol blowing agents, HCs, and methyl formate are flammable, and the others are nonflammable. The flammability hazards of the flammable compounds in this end-use can be adequately addressed in the process of meeting OSHA regulations and fire codes. In this end-use, HFC–134a, Formacel TI, HFC–245fa, HFC–365mfc, and Formacel Z–6 have significantly higher GWPs than the other available substitutes mentioned above in this paragraph, thereby increasing overall risks to human health and the environment.

vii. Rigid Polyurethane and Polyisocyanurate Laminated Boardstock

For rigid polyurethane and polyisocyanurate laminated boardstock, saturated light HCs (C3–C6), CO₂, water, ecomate™, Exxsol blowing agents, methyl formate, HFC–152a, HFO–1234ze(E), and *trans*-1-chloro-3,3,3-trifluoroprop-1-ene are acceptable alternatives with GWPs that range from zero to 124. Toxicity is not a significant concern for these alternatives because they may be used for blowing laminated boardstock consistent with required or recommended workplace exposure limits. With the exception of HCs and Exxsol blowing agents, these

⁵⁴ UNEP, 2013. Report of the Technology and Economic Assessment Panel, Volume 2: Decision XXIV/7 Task Force Report, Additional Information on Alternatives to ODS. September, 2013.

⁵⁵ UNEP, 2010. Report of the Rigid and Flexible Foams Technical Options Committee, 2010 Assessment. This document is accessible at http://ozone.unep.org/Assessment_Panels/TEAP/Reports/FTOC/FTOC-2010-Assessment-Report.pdf.

alternatives contain compounds that are exempt from the definition of VOC. Of the alternatives listed above, only trans-1-chloro-3,3,3-trifluoroprop-1-ene has an ODP and as discussed above for rigid polyurethane appliance foam, trans-1-chloro-3,3,3-trifluoroprop-1-ene's impact on global atmospheric ozone abundance is expected to be statistically insignificant. Of the various options listed in this paragraph, ecomate™, Exxsol blowing agents, HCs, and methyl formate are flammable, and the others are nonflammable. The flammability hazards of the flammable compounds in this end-use can be adequately addressed in the process of meeting OSHA regulations and fire codes. In this end-use, HFC-134a, HFC-245fa, and HFC-365mfc have significantly higher GWPs than the other available substitutes mentioned above in this paragraph, thereby increasing overall risks to human health and the environment.

viii. Polystyrene Extruded Sheet

For polystyrene extruded sheet, acceptable substitutes include saturated light hydrocarbons (C3–C6), CO₂, water, Exxsol blowing agents, ecomate™ (methyl formate), and HFC-152a. These substitutes have GWPs ranging from 1 to 124. Toxicity is not a significant concern for these alternatives because they may be used for blowing extruded polystyrene foam consistent with required or recommended workplace exposure limits. With the exception of HCs and Exxsol blowing agents, these substitutes contain compounds that are exempt from the definition of VOC. Of the substitutes listed above in this paragraph, all have an ODP of zero. Of the various substitutes listed in this paragraph, ecomate™, Exxsol blowing agents, HFC-152a, and HCs are flammable, and the others are nonflammable. The flammability hazards of the flammable compounds in this end-use can be adequately addressed in the process of meeting OSHA regulations and fire codes. In this end-use, HFC-134a, HFC-245fa, HFC-365mfc, Formacel TI and Formacel Z-6 have significantly higher GWPs than the other available substitutes mentioned above in this paragraph, thereby increasing overall risks to human health and the environment.

ix. Polystyrene Extruded Boardstock and Billet

For polystyrene extruded boardstock and billet, acceptable substitutes include saturated light hydrocarbons (C3–C6), CO₂, water, Exxsol blowing agents, ecomate™ (methyl formate), HFC-152a, and HFO-1234ze(E). These

substitutes have GWPs ranging from 1 to 124. Toxicity is not a significant concern for these alternatives because they may be used for blowing extruded polystyrene foam consistent with required or recommended workplace exposure limits. With the exception of HCs and Exxsol blowing agents, these substitutes contain compounds that are exempt from the definition of VOC. Of the substitutes listed above in this paragraph, all have an ODP of zero. Of the various substitutes listed in this paragraph, ecomate™, Exxsol blowing agents, HFC-152a, and HCs are flammable, and the others are nonflammable. The flammability hazards of the flammable compounds in this end-use can be adequately addressed in the process of meeting OSHA regulations and fire codes. In this end-use, HFC-134a, HFC-245fa, HFC-365mfc, Formacel B and Formacel Z-6 have significantly higher GWPs than the other available substitutes mentioned above in this paragraph, thereby increasing overall risks to human health and the environment.

x. Integral Skin Polyurethane

In integral skin polyurethane, which includes foam in car steering wheels, dashboards, and shoe soles, substitutes include acetone, saturated light HCs (C3–C6), CO₂, water, Exxsol blowing agents, methyl formate, ecomate™, HFO-1234ze(E), HFC-152a, and trans-1-chloro-3,3,3-trifluoroprop-1-ene. These substitutes have GWPs ranging from zero to 124. Toxicity is not a significant concern for these alternatives because they may be used for blowing integral skin polyurethane foam consistent with required or recommended workplace exposure limits. With the exception of HCs and Exxsol blowing agents, these substitutes contain compounds that are exempt from the definition of VOC. Of the substitutes listed above, only trans-1-chloro-3,3,3-trifluoroprop-1-ene has an ODP and as discussed above for rigid polyurethane appliance foam, its impact on global atmospheric ozone abundance is expected to be statistically insignificant. Of the various substitutes listed in this paragraph, acetone, methyl formate, ecomate™, Exxsol blowing agents, HFC-152a, and hydrocarbons are flammable, and the others are nonflammable. The flammability hazards of the flammable compounds in this end-use can be adequately addressed in the process of meeting OSHA regulations and fire codes. In this end-use, HFC-134a, HFC-245fa, HFC-365mfc, Formacel TI, and Formacel Z-6 have significantly higher GWPs than the other available substitutes mentioned above in this paragraph,

thereby increasing overall risks to human health and the environment.

xi. Polyolefin Foam

For polyolefin foam, saturated light HCs (C3–C6), CO₂, water, ecomate™, Exxsol blowing agents, methyl formate, HFC-152a, blends of HFC-152a and saturated light HCs, HFO-1234ze(E), and trans-1-chloro-3,3,3-trifluoroprop-1-ene are acceptable alternatives with GWPs that range from zero to 124. Toxicity is not a significant concern for these alternatives because they may be used for blowing polyolefin foam consistent with required or recommended workplace exposure limits. With the exception of HCs, HC blends, and Exxsol blowing agents, these alternatives contain compounds that are exempt from the definition of VOC. Of the substitutes listed above in this paragraph, all have an ODP of zero. Of the various options listed in this paragraph, ecomate™, Exxsol blowing agents, HCs, and methyl formate are flammable, and the others are nonflammable. The flammability hazards of the flammable compounds in this end-use can be adequately addressed in the process of meeting OSHA regulations and fire codes. In this end-use, HFC-134a, Formacel TI, HFC-245fa, HFC-365mfc, and Formacel Z-6 have significantly higher GWPs than the other available substitutes mentioned above in this paragraph, thereby increasing overall risks to human health and the environment.

xii. Phenolic Insulation Board and Bunstock

In phenolic insulation board and bunstock, which includes insulation for roofing and walls, acceptable substitutes include saturated light HCs (C3–C6), CO₂, 2-chloropropane, water, Exxsol blowing agents, ecomate™, HFO-1234ze(E), and HFC-152a. These substitutes have GWPs ranging from 1 to 124. Toxicity is not a significant concern for these alternatives because they may be used for blowing phenolic foam consistent with required or recommended workplace exposure limits. With the exception of 2-chloropropane, hydrocarbons, and Exxsol blowing agents, these substitutes contain compounds that are exempt from the definition of VOC. Of the substitutes listed above in this paragraph, all have an ODP of zero. Of the various substitutes listed in this paragraph, 2-chloropropane, ecomate™, Exxsol blowing agents, HFC-152a, and HCs are flammable, and the others are nonflammable. The flammability hazards of the flammable compounds in this end-use can be adequately

addressed in the process of meeting OSHA regulations and fire codes. In this end-use, HFC–143a, HFC–134a, HFC–245fa, and HFC–365mfc have significantly higher GWPs than the other available substitutes mentioned above in this paragraph, thereby increasing overall risks to human health and the environment.

For the foam end-uses listed above, both fluorinated and non-fluorinated substitutes are being used today in the U.S.; EPA recognizes that the formulator and systems house will consider other criteria including toxicity, flammability, and local air quality. However, given the range of substitutes available, we believe that there are other alternatives available for formulators or systems houses that pose less risk for human health and the environment than the HFCs and HFC blends proposed to be listed as unacceptable.

c. How does EPA propose to regulate foams and products containing foams?

EPA is proposing to regulate foam blowing agents contained in the cells of closed cell foams and proposes to consider these foams and products containing them to be subject to the proposed unacceptability determinations, as well as the use of the foam blowing agent in manufacturing those products. Section 612(c) of the Clean Air Act refers to “replacing” ODS with substitutes. In the case of the foam blowing agent sector, we have previously interpreted unacceptability determinations as referring solely to replacing the foam blowing agent and have not interpreted the SNAP lists to apply to products made with foam. Thus, an unacceptable foam blowing agent may not be used in or imported into the United States. However, products made with unacceptable foams blown overseas may be imported. For example, refrigerators containing appliance foam blown with the unacceptable blowing agent HCFC–141b may still be imported into the United States, even though the SNAP program has listed HCFC–141b as an unacceptable foam blowing agent (September 30, 2004 at 69 FR 58269). Under this interpretation of our SNAP regulations if this proposal becomes final the foam blowing agents we are proposing to find unacceptable would be prohibited from being used or imported into the United States, but foam products or products containing foam, such as appliances or furniture made with these unacceptable foam blowing agents, could be imported.

In this rule, EPA is proposing to adopt a different interpretation for closed cell foams that would result in prohibiting

both import and manufacture of products made with the blowing agents proposed to be unacceptable. This approach would have an effect similar to the earlier nonessential product ban for products containing unacceptable foam blowing agents, prohibiting import and distribution of such products. For closed cell foams, the blowing agents are retained in cells after the foam is blown and provide insulation value. Foam blowing end-uses that contain closed-cell foams include rigid polyurethane appliance foam; rigid polyurethane: Spray, commercial refrigeration, and sandwich panels; rigid polyurethane (slabstock and other); rigid polyurethane and polyisocyanurate laminated boardstock; polystyrene (extruded sheet); polystyrene: extruded boardstock and billet; polyolefin; and phenolic insulation board and bunstock. Foam blowing end-uses containing open cell foams include flexible polyurethane and integral skin polyurethane. In comparison, in open cell foams, the blowing agent is not retained and would have escaped prior to import. Thus, an open cell product blown with an unacceptable foam blowing agent (or products containing such an open cell foam) would not contain any of that agent when imported in the United States whereas a closed cell product would still retain some of the foam blowing agent. EPA is proposing and is seeking comment on whether the Agency should consider use of the foam blowing agent to apply to products with closed cell foam since the product still contains at least some of the foam blowing agent and thus is replacing other foam blowing agents. EPA is also seeking comment on whether the Agency should consider use of the foam blowing agent to apply to open cell foam and products containing open cell foam, and in particular on what would be the legal basis for doing so.

d. When would the listings change?

Through this action, EPA is proposing to change the listings for foam blowing agents as of January 1, 2017. Based on information concerning the timeframes from past transitions, EPA believes this date allows sufficient opportunity to redesign for a different foam blowing agent. However, EPA is seeking comment on changing the listings as of January 1, 2016. The foam industry was able to convert from HCFC–142b and HCFC–22 to other acceptable substitutes between EPA’s proposed unacceptability determination in November 2005 and its final determination in March 2007, which specified that existing users of the unacceptable HCFCs must transition by

March 1, 2008, for most uses. EPA also provided an additional 18 months for this transition for marine flotation foam, to September 1, 2009, and allowed until January 1, 2010, for a transition away from HCFC–22 and HCFC–142b in extruded polystyrene foam boardstock (March 28, 2007; 72 FR 14432). EPA is requesting comment on using January 1, 2017 as the date on which foam must not be blown using HFC–134a, HFC–365mfc, HFC–245fa, HFC–143a and blends thereof, or Formacel B, Formacel TI, and Formacel Z–6. We are also seeking comment on whether a transition could be completed by January 1, 2016. In particular, we request comment on whether these dates would be sufficient time for the transition where the foam product is incorporated into a larger product (e.g., commercial refrigeration foam used in transport refrigeration), and whether there are any specific foam end-uses or applications that may require additional time and, if so, how long and why. Based on this information, EPA could consider grandfathering options for foam blowing agents in specific end-uses or could provide a different date for use to be unacceptable.

e. Narrowed Use Limits for Military or Space- and Aeronautics-Related Applications

EPA is proposing an exception to the proposed unacceptability determination for HFC and HFC blend foam blowing agents for military or space- and aeronautics-related applications. EPA is also proposing that the narrowed use limit would expire on January 1, 2022. Under a narrowed use limit, the end user for a military or space- and aeronautics application would need to ascertain that other alternatives are not technically feasible and document the results of their analysis. See 40 CFR 82.180(b)(3). For the military, there are several unique performance requirements related to weapon systems that require extensive testing prior to qualifying alternatives for HFC-containing foams. While the vast majority of applications for foams are anticipated to be able to transition to acceptable alternatives by the proposed January 1, 2017 date, in a very small number of cases, the timeframes associated with testing and qualifications for weapon systems could take longer. In addition, some of the lower-GWP alternatives may not be available at this time in certain specialty applications with unique military requirements such as undersea; aerospace; and chemical, biological, and radiological warfare systems. In the case of space- and aeronautics-related

applications, HFCs are used in numerous applications, including certain mission-critical applications such as foam blowing for which appropriate substitutes have not yet been identified. Past experience indicates that transitions away from CFC- and HCFC-blown foams in similar applications took several years due to the challenging operational environment and the lengthy requalification process associated with human-rated space flight systems.

Under the acceptable for narrowed use limits category, users of a restricted agent within the narrowed use limits category must make a reasonable effort to ascertain that other substitutes or alternatives are not technically feasible. Users are expected to undertake a thorough technical investigation of alternatives to the otherwise restricted substitute. Although users are not required to report the results of their investigations to EPA, users must document these results, and retain them in their files for the purpose of demonstrating compliance.

Under a narrowed use limit, the end user for a military or space- and aeronautics- related application would need to ascertain that other alternatives are not technically feasible and document the results of their analysis. See 40 CFR 82.180(b)(3). Documentation should include descriptions of:

- Process or product in which the substitute is needed;
- Substitutes examined and rejected;
- Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or
- Anticipated date other substitutes will be available and projected time for switching.

EPA is seeking comment on this proposed narrowed use limitation for military or space- and aeronautics-related applications. In addition, EPA is also seeking comment on the timeframe for this narrowed use limitation, recognizing that if all alternatives are not qualified in advance of 2022, the Agency may need to revisit and adjust the end date.

f. Summary

EPA seeks comments on changing the listings for the proposed foam end-uses. In particular, EPA is interested in whether there are specific uses other than spray foam that require the use of HFC-134a, HFC-365mfc, HFC-245fa, and blends thereof, or the blends Formacel B, Formacel TI, or Formacel Z-6 for reasons of fire safety or technical feasibility. We request comment on whether closed cell foam products and products containing

closed cell foams should be subject to the unacceptability determinations, which under our current interpretation would otherwise only apply to the use of the foam blowing agent. We also seek comment on whether the Agency should consider use of the foam blowing agent to apply to open cell foam and products containing open cell foam, and in particular what would be the legal basis for doing so. EPA also requests comment on whether the proposed date provides an appropriate length of time for transition and whether there should be different dates for certain foam end-uses due to technical challenges that may exist for some foam end-uses but not all. EPA is also interested in information concerning the supply of substitutes in sufficient quantities to meet a domestic transition in the timeframe proposed in this action. EPA also takes comment on the proposed exception for military or space- and aeronautics-related applications as described above.

VI. What is EPA proposing for HCFCs?

EPA is proposing to modify the listings for three HCFCs in certain end-uses because the three HCFCs are subject to the use restrictions in CAA section 605(a) and EPA's implementing regulations at 40 CFR part 82 subpart A. Additionally, the nonessential products ban under CAA section 610 also restricts sale and distribution of certain products containing or manufactured with these three HCFCs. We believe it is important that the SNAP listings not indicate that these HCFCs may be used when another program under title VI of the CAA would prevent such use. Thus, we are proposing to align the requirements. The HCFCs addressed in this rule are listed as acceptable or acceptable subject to use conditions in the aerosols, foam blowing agents, fire suppression and explosion protection agents, sterilants, and adhesives, coatings and inks sectors. This in addition to the proposed unacceptability of HCFC-containing refrigerants in MVAC systems (see section V.B. of this preamble).

A. What are the proposed modifications to the listings for the three HCFCs and in which end-uses?

EPA is proposing to modify the listings for HCFC-141b, HCFC-142b, and HCFC-22, as well as blends that contain these substances, from acceptable to unacceptable in all sectors⁵⁶ except refrigeration and air

conditioning. EPA is not addressing HCFC use for refrigeration and air conditioning because CAA section 605(a) and our implementing regulations allows for continuing use of HCFCs to service equipment. We are proposing that the listings would be modified 60 days following issuance of a final rule promulgating this proposal.

B. Why is EPA modifying the listings for HCFCs?

EPA is proposing to modify the listings for these three HCFCs and blends containing these HCFCs to align the SNAP listings with other Title VI regulations, specifically section 605 and its implementing regulations at 40 CFR part 82 subpart A and section 610 and its implementing regulations at 40 CFR part 82 subpart C.

1. Alignment of SNAP Listings for the Three HCFCs With Regulations Implementing CAA Sections 605 and 610

CAA Section 605(a) explicitly prohibits the introduction into interstate commerce or the use of any class II substance as of January 1, 2015, unless such substance:

- (1) Has been used, recovered, and recycled;
- (2) is used and entirely consumed (except for trace quantities) in the production of other chemicals;
- (3) is used as a refrigerant in appliances manufactured prior to January 1, 2020; or
- (4) is listed as acceptable for use as a fire suppression agent for nonresidential applications in accordance with section 612(c).

Through rulemaking, EPA accelerated to January 1, 2010, the prohibitions on use and introduction into interstate commerce for HCFC-141b, HCFC-22, and HCFC-142b that has not been used, recovered, and recycled. See 40 CFR 82.15(g). With respect to refrigeration and air conditioning uses, EPA's implementing regulations prohibit the use and introduction into interstate commerce of these HCFCs, unless used, recovered, and recycled, in equipment manufactured on or after January 1, 2010. EPA's proposal to modify the listings for HCFC-141b, HCFC-22, and HCFC-142b, including blends that contain these HCFCs, in various applications is consistent with the accelerated dates contained in our implementing regulations and covers end-uses where these HCFCs have previously been listed as acceptable as aerosols, refrigerants, foam blowing agents, fire suppressants, cleaning solvents, sterilants, and adhesives, coatings and inks.

⁵⁶ These three HCFCs have previously been listed as unacceptable in several, but not all, SNAP sectors.

Section 605(a) complements section 610, which prohibited the sale and distribution, as well as offer for sale and distribution, in interstate commerce of aerosol products and pressurized dispensers containing a class II substance (i.e., HCFCs), and plastic foam products containing or manufactured with a class II substance, with limited exceptions.⁵⁷ This statutory prohibition took effect on January 1, 1994. Consequently, most foams and aerosols have not used HCFCs since 1994.

Recognizing that other HCFCs are not yet subject to the use and interstate commerce prohibitions in section 605 and 40 CFR 82.15(g), EPA is not proposing to change the SNAP listings for HCFCs other than HCFC-141b, -142b, and -22 and blends containing those substances at this time. EPA may revisit the acceptability of other HCFCs in a later rulemaking as appropriate.

2. Anticipated Effects

EPA does not anticipate that these changes will have a significant effect on the use of HCFC-141b, -142b, and -22 since existing regulations limit the use of these three HCFCs (unless used, recovered, and recycled) in almost all end-uses in the United States (see 40 CFR 82.15(g)). For the sectors addressed in this rulemaking, EPA is not aware of anyone using recovered, recycled or reclaimed HCFC-22, HCFC-141b and HCFC-142b. In addition, as a result of the use restrictions in CAA section 605 and 40 CFR 82.15(g), as well as the sale and distribution restrictions on certain products containing or manufactured with these substances in CAA section 610 and 40 CFR part 82 subpart C, most sectors have taken significant steps to transition to non-ODS substitutes. For example, HCFCs in aerosol applications have been replaced by HCs, HFO-1234ze, roll-ons, pump sprays, and HFC-152a, excluding some niche technical applications that still rely on HCFCs not addressed in this action. HCFCs in foam blowing agents have largely been replaced by, among other things, methyl formate, HCs, Solstice-1233zd(E), and carbon dioxide; any remaining HCFC use in this sector is limited to HCFCs not addressed in this action. For these reasons, we believe it is technically feasible for sources to comply with the proposed changes to the listings for these three HCFCs within 60 days of a final rule issued consistent with this proposal.

EPA seeks comment on its proposal to modify the listings for HCFC-141b, -142b, -22, and blends containing these substances. EPA is particularly interested in comments on both the scope of the proposed modifications and the timing.

VII. Do SNAP requirements apply to exports and imports?

The requirements of the SNAP program apply to both exports and imports. EPA understands that some manufacturers may be interested in whether the listing decisions, if finalized as proposed, would apply to their products. EPA has previously responded to comments about the applicability of the SNAP program to products destined for export. Most recently, in a final rule issued December 20, 2011, EPA responded to a comment concerning whether appliances manufactured for export should be allowed to have larger charge sizes than those being sold in the United States (and thus not have to comply with the use conditions being established in that rule). EPA stated that:

Under section 612 of the Clean Air Act, the SNAP program is applicable to any person introducing a substitute into interstate commerce. Interstate commerce is defined in 40 CFR 82.104(n) as: The distribution or transportation of any product between one state, territory, possession or the District of Columbia, and another state, territory, possession or the District of Columbia, or the sale, use or manufacture of any product in more than one state, territory, possession or the District of Columbia. The entry points for which the product is introduced into interstate commerce are the release of a product from the facility in which the product was manufactured, the entry into a warehouse from which the domestic manufacturer releases the product for sale or distribution, and at the site of United States Customs clearance. This definition applies to any appliances produced in the United States, including appliances that will be exported. (76 FR 78846)

Therefore, EPA concluded that the same use conditions apply to appliances being exported.

The range of sectors and end-uses covered by the SNAP program varies. Some end-uses, such as the refrigeration and air conditioning sector, includes appliances charged by OEMs and appliances typically field-charged. Some appliances charged by OEMs are hermetically sealed and other appliances are not. Furthermore, these appliances differ from products such as

aerosols or foams because of the potential for servicing the appliances throughout their use. Some manufacturers of motor vehicle air conditioners identified a potential concern that there may be a lack of servicing infrastructure for low-GWP alternatives in markets outside the U.S. EPA recognizes that the transition to alternatives may occur at a different pace in different global markets. For example, the European Union is planning to transition to low-GWP alternatives for MVACs in 2017 which is several years earlier than what EPA is proposing. However, other countries have not indicated any specific plan to transition to low-GWP alternatives for MVACs. If finalized as proposed, HFC-134a would be listed as unacceptable in model year 2021 and the unacceptability listing would include MVACs that will be exported.

EPA applies the SNAP requirements equally to imports and exports. However, EPA understands the concerns for proper infrastructure for servicing appliances in markets outside the U.S. EPA believes there is ample time between now and model year 2021 for such infrastructure to be established. EPA welcomes comments and specific information on this topic.

VIII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order (E.O.) 12866 (58 FR 51735, October 4, 1993), this action is a “significant regulatory action.” It raises novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under E.O. 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

EPA conducted an analysis⁵⁸ that considered the economic impacts of this proposed rule on small entities, as further discussed in the section C below. The analysis also considered that, specific to refrigerants used in air conditioning systems for newly manufactured light-duty vehicles, there are considerable environmental benefits of a transition to alternative refrigerants and there are costs associated with those substitutions. Based on recent information in manufacturers’ product

⁵⁷ Section 610(d) contains certain exceptions and also authorizes EPA to grant exceptions in specific circumstances. For the complete list of exceptions, see EPA’s implementing regulations at 40 CFR part 82, subpart C.

⁵⁸ ICF International. Economic Impact Screening Analysis for Regulatory Options to Change Listing Status of High-GWP Alternatives, 2014.

plans, a limited number of manufacturers may have been planning to meet the GHG standards but still continue to use HFC-134a beyond MY 2021 for a limited number of their models. However, we believe there is time for any such manufacturers to make appropriate adjustments. These manufacturers could incur costs attributable to this proposal (representing the proposed requirement to cease use of HFC-134a by MY 2021), but there would be environmental benefits in the form of increased reductions of GHG emissions from MVAC systems which would not otherwise occur, assuming these manufacturers also continue with their plans to achieve the reductions by means other than substitution of MVAC refrigerant.

B. Paperwork Reduction Act

This action does not impose any new information collection burden. This proposed rule is an Agency determination. It contains no new requirements for reporting. The Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations in subpart G of 40 CFR part 82 under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060-0226. This Information Collection Request (ICR) included five types of respondent reporting and recordkeeping activities pursuant to SNAP regulations: Submission of a SNAP petition, filing a SNAP/TSCA Addendum, notification for test marketing activity, recordkeeping for substitutes acceptable subject to use restrictions, and recordkeeping for small volume uses. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15.C.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice-and-comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the Agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a

small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After conducting an analysis⁵⁹ that considered the economic impacts of this proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The requirements of this proposed rule with respect to HFCs, if finalized as proposed, would impact manufacturers of some consumer and technical aerosol products, retail food refrigeration equipment, vending machines, motor vehicles, and products containing phenolic, polyisocyanurate, polyolefin, polyurethane, and polystyrene foams. The requirements of this proposed rule with respect to HCFCs, if finalized as proposed, would affect manufacturers of aerosols, foams, solvent cleaning, fire suppression, and adhesives, coatings, and inks. This rule's provisions do not create enforceable requirements for refrigeration and air conditioning technicians, but they would indirectly affect technicians servicing motor vehicle air conditioning systems, retail food refrigeration equipment, and vending machines where the technician, rather than the refrigeration or AC equipment owner, purchases servicing equipment for different refrigerants. EPA expects these indirect impacts on technicians are minimal, because the transitions to different refrigerants required by this rule are already occurring due to other regulations (e.g., light duty vehicle GHG rule) and corporate social responsibility initiatives (e.g., Consumer Goods Forum pledge concerning HFC refrigerants), and because many of the still-acceptable alternatives are already used for these refrigeration or air conditioning equipment types. Further, most acceptable HFC refrigerant blends can be recovered and serviced using equipment that service technicians already own. In some uses, there is no significant impact of the proposed rule because the substitutes proposed to be prohibited are not widely used (e.g., use of HFC-134a as a propellant in consumer aerosol products, use of HFC-134a as a foam blowing agent in various polyurethane foams). A significant portion of the businesses regulated under this rule are not small businesses

(e.g., car manufacturers, appliance manufacturers). About 500,000 small businesses could be subject to the rulemaking, although more than 99% of small businesses subject to this proposed rulemaking would be expected to experience zero compliance costs. EPA continues to be interested in the potential impacts of the proposed rule on small entities and welcomes comments on issues related to such impacts, in particular technical challenges, including time to transition, that may exist for some small entities but not all.

D. Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandate Reform Act of 1995 (UMRA), 2 U.S.C. 1531-1538 for State, local, or tribal governments or the private sector. This action imposes no enforceable duty on any State, local, or tribal governments. The enforceable requirements of this proposed rule related to prohibiting certain substitutes, including HFC-134a, R-404A and R-507A, would require new equipment to be manufactured using other available options but would not require changes to existing equipment that is already manufactured or purchased. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA. This action is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. This regulation applies directly to facilities that use these substances and not to governmental entities.

E. Executive Order 13132: Federalism

This action does not have Federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This regulation applies directly to facilities that use these substances and not to governmental entities. Thus, Executive Order 13132 does not apply to this action. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comments on this proposed action from State and local officials.

⁵⁹ ICF International. Economic Impact Screening Analysis for Regulatory Options to Change Listing Status of High-GWP Alternatives, 2014.

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

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. EPA specifically solicits additional comment on this proposed action from tribal officials.

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

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in E.O. 12866, and because the Agency does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This proposed rule restricts the use of certain substitutes that have greater overall risks for human health and the environment, primarily due to their high global warming potential. The reduction in GHG emissions would provide climate benefits for all people, including benefits for children and future generations. The public is invited to submit comments or identify peer-reviewed studies and data that assess effects of early life exposure to the alternatives addressed in this action.

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

This action is not a “significant energy action” as defined in Executive Order 13211, (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Aerosol uses are not related to the supply, distribution, or use of energy. For the end-uses that are related to energy effects such as refrigeration and air conditioning, a number of alternatives are available to replace those refrigerants that are proposed as unacceptable in this action; many of the alternatives are as energy efficient or more energy efficient than the substitutes being proposed as unacceptable. Thus, we have concluded that this rule is not likely to have any adverse energy effects.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (“NTTAA”), Public Law 104–113, (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This proposed rule does not involve technical standards.

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

Executive Order (E.O.) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. This proposed rule, if finalized, would prohibit a number of substances with ODPs or high GWPs. The reduction in ODS and GWP emissions would assist in restoring the stratospheric ozone layer and provide climate benefits.

IX. References

This preamble references the following documents, which are also in the Air Docket at the address listed in Section I.B.1. Unless specified otherwise, all documents are available electronically through the Federal

Docket Management System, Docket # EPA–HQ–OAR–2014–0198.

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List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Recycling, Reporting and recordkeeping requirements, Stratospheric ozone layer.

Dated: July 9, 2014.

Gina McCarthy,
Administrator.

For the reasons stated in the preamble, EPA proposes to amend 40 CFR part 82 as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

■ 1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

Subpart G—Significant New Alternatives Policy Program

■ 2. Amend Subpart G by adding Appendix U to read as follows:

Appendix U to Subpart G of Part 82—Unacceptable Substitutes and Substitutes Subject To Use Restrictions Listed in the [DATE OF PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER] Final Rule, Effective [DATE 60 DAYS AFTER PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER].

TABLE 1—AEROSOLS—UNACCEPTABLE SUBSTITUTES

End-use	Substitute	Decision	Further information
Propellants	HFC-125	Unacceptable as of January 1, 2016	HFC-125 has a Chemical Abstracts Service Registry Number (CAS Reg. No.) of 354-33-6 and it is also known by the name 1,1,1,2,2-pentafluoropropane. HFC-125 has a high GWP of 3,500. Other substitutes are available for this end-use with lower overall risk to human health and the environment. Products using this propellant that are manufactured prior to January 1, 2016 may be sold, imported, exported, distributed and used after that date.
Propellants	HCFC-22 and HCFC-142b.	Unacceptable effective [DATE 60 DAYS AFTER PUBLICATION OF FINAL RULE]	Use or introduction into interstate commerce of virgin HCFC-22 and HCFC-142b for aerosols is prohibited as of January 1, 2010 under EPA's regulations at 40 CFR part 82 subpart A. These propellants have ozone depletion potentials of 0.055 and 0.065, respectively.
Solvents	HCFC-141b	Unacceptable effective [DATE 60 DAYS AFTER PUBLICATION OF FINAL RULE]	Use or introduction into interstate commerce of virgin HCFC-141b for aerosols is prohibited as of January 1, 2015 under EPA's regulations at 40 CFR part 82 subpart A. HCFC-141b has an ozone depletion potential of 0.11.

TABLE 2—SUBSTITUTES ACCEPTABLE SUBJECT TO USE CONDITIONS

End-use	Substitute	Decision	Use conditions	Further information
Propellants	HFC-134a	Acceptable subject to use conditions.	As of January 1, 2016, acceptable only for use in: • Metered dose inhalers for the treatment of asthma and chronic obstructive pulmonary disease, allergic rhinitis, and other diseases where aerosols can be used for systemic delivery through lung, nose, or other organs • cleaning products for removal of grease, flux and other soils from electrical equipment or electronics • lubricants for electrical equipment or electronics • sprays for aircraft maintenance • pesticides for use near electrical wires or in aircraft, in total release insecticide foggers, or in certified organic use pesticides for which EPA has specifically disallowed all other lower-GWP propellants mold release agents • lubricants and cleaners for spinnerettes for synthetic fabrics • duster sprays specifically for removal of dust from photographic negatives, semiconductor chips, and specimens under electron microscopes • document preservation sprays • wound care sprays topical coolant sprays for pain alleviation products for removing bandage adhesives from skin.	HFC-134a has a Chemical Abstracts Service Registry Number (CAS Reg. No.) of 811-97-2 and it is also known by the name 1,1,1,2-tetrafluoropropane. HFC-134a has a relatively high GWP of 1,430. Use is allowed for the specified uses because of the greater technical and safety demands in these applications compared to other aerosol applications. It is prohibited to use aerosol products other than those specified here using HFC-134a that are manufactured on or after January 1, 2016. Aerosol products using this propellant that are manufactured prior to January 1, 2016 may be sold, imported, exported, distributed and used after that date.

TABLE 2—SUBSTITUTES ACCEPTABLE SUBJECT TO USE CONDITIONS—Continued

End-use	Substitute	Decision	Use conditions	Further information
Propellants	HFC–227ea ..	Acceptable subject to use conditions.	As of January 1, 2016, acceptable only for use in metered dose inhalers for the treatment of asthma and chronic obstructive pulmonary disease.	HFC–227ea has a Chemical Abstracts Service Registry Number (CAS Reg. No.) of 431–89–0 and it is also known by the name 1,1,1,2,3,3,3-heptafluoropropane. HFC–227ea has a relatively high GWP of 3,220. Use is allowed for metered dose inhalers because of the greater technical and safety demands in this application compared to other aerosol applications. It is prohibited to use aerosol products other than metered dose inhalers using HFC–227ea that are manufactured on or after January 1, 2016. Aerosol products using this propellant that are manufactured prior to January 1, 2016 may be sold, imported, exported, distributed and used after that date.

TABLE 3—REFRIGERATION AND AIR CONDITIONING—UNACCEPTABLE SUBSTITUTES

End-use	Substitute	Decision	Further information
Retail food refrigeration (new and retrofit).	R–404A	Unacceptable as of January 1, 2016.	R–404A is a blend, by weight, of 44% HFC–125, 4% HFC–134a, and 52% HFC–143a. It has a high GWP of approximately 3,920. Other substitutes are available for this end-use with lower overall risk to human health and the environment.
Retail food refrigeration (new and retrofit).	R–507A	Unacceptable as of January 1, 2016.	R–507A is a blend, by weight, of 50% HFC–125 and 50% HFC–143a. It has a high GWP of approximately 3,990. Other substitutes are available for this end-use with lower overall risk to human health and the environment.
Retail food refrigeration (condensing units and supermarket systems)(new).	HFC–227ea, R–407B, R–421B, R–422A, R–422C, R–422D, R–428A, R–434A.	Unacceptable as of January 1, 2016.	These refrigerants have GWPs ranging from 2,729 to 3,607. Other substitutes are available for this end-use with lower overall risk to human health and the environment.
Retail food refrigeration (condensing units and supermarket systems)(retrofit).	R–407B, R–421B, R–422A, R–422C, R–422D, R–428A, R–434A.	Unacceptable as of January 1, 2016.	These refrigerants have GWPs ranging from 2,729 to 3,607. Other substitutes are available for this end-use with lower overall risk to human health and the environment.
Retail food refrigeration (stand-alone units only) (new only).	HFC–134a	Unacceptable as of January 1, 2016.	HFC–134a has a Chemical Abstracts Service Registry Number (CAS Reg. No.) of 811–97–2 and it is also known by the name 1,1,1,2-tetrafluoropropane. HFC–134a has a relatively high GWP of 1,430. Other substitutes are available for this end-use with lower overall risk to human health and the environment.
Retail food refrigeration (stand-alone units only) (new only).	FOR12A, FOR12B, HFC–227ea, IKON B, KDD6, R–125/290/134a/600a (55.0/1.0/42.5/1.5), R–407A, R–407B, R–407C, R–407F, R–410A, R–410B, R–417A, R–421A, R–421B, R–422A, R–422B, R–422C, R–422D, R–424A, R–426A, R–428A, R–434A, R–437A, R–438A, RS–24 (2002 formulation), RS–44 (2003 formulation), SP34E, THR–03.	Unacceptable as of January 1, 2016.	These refrigerants have GWPs ranging from approximately 550 to 3,607. Other substitutes are available for this end-use with lower overall risk to human health and the environment.
Vending machines (new and retrofit).	R–404A	Unacceptable as of January 1, 2016.	R–404A is a blend, by weight, of 44% HFC–125, 4% HFC–134a, and 52% HFC–143a. It has a GWP of approximately 3,920. Other substitutes are available for this end-use with lower overall risk to human health and the environment.

TABLE 3—REFRIGERATION AND AIR CONDITIONING—UNACCEPTABLE SUBSTITUTES—Continued

End-use	Substitute	Decision	Further information
Vending machines (new and retrofit).	R-507A	Unacceptable as of January 1, 2016.	R-507A is a blend, by weight, of 50% HFC-125 and 50% HFC-143a. It has a GWP of approximately 3,990. Other substitutes are available for this end-use with lower overall risk to human health and the environment.
Vending machines (new only).	HFC-134a	Unacceptable as of January 1, 2016.	HFC-134a has a Chemical Abstracts Service Registry Number (CAS Reg. No.) of 811-97-2 and it is also known by the name 1,1,1,2-tetrafluoropropane. HFC-134a has a relatively high GWP of 1,430. Other substitutes are available for this end-use with lower overall risk to human health and the environment.
Vending machines (new only).	FOR12A, FOR12B, IKON B, KDD6, R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-407C, R-410A, R-410B, R-417A, R-421A, R-422B, R-422C, R-422D, R-426A, R-437A, R-438A, RS-24 (2002 formulation), SP34E.	Unacceptable as of January 1, 2016.	These refrigerants have GWPs ranging from approximately 550 to 3,085. Other substitutes are available for this end-use with lower overall risk to human health and the environment.
Motor vehicle air conditioning (new equipment in passenger cars and light-duty trucks only).	HFC-134a	Unacceptable as of Model Year (MY) 2021.	HFC-134a has a Chemical Abstracts Service Registry Number (CAS Reg. No.) of 811-97-2 and it is also known by the name 1,1,1,2-tetrafluoropropane. HFC-134a has a relatively high GWP of 1,430. Other substitutes are available for this end-use with lower overall risk to human health and the environment.
Motor vehicle air conditioning (new equipment in passenger cars and light-duty trucks only).	R-406A, R-414A (HCFC Blend Xi, GHG-X4), R-414B (HCFC Blend Omicron), HCFC Blend Delta (Free Zone), Freeze 12, GHG-X5, HCFC Blend Lambda (GHG-HP).	Unacceptable as of MY 2017.	These refrigerants all contain HCFCs. They have GWPs ranging from 1,480 to 2,340 and ODPs ranging from 0.012 to 0.056. Other substitutes are available for this end-use with lower overall risk to human health and the environment.
Motor vehicle air conditioning (new equipment in passenger cars and light-duty trucks only).	R-416A (FRIGC FR-12, HCFC Blend Beta).	Unacceptable as of MY 2017.	This blend has a relatively high GWP of approximately 1,080 and an ODP of approximately 0.008. Other substitutes are available for this end-use with lower overall risk to human health and the environment.
Motor vehicle air conditioning (new equipment in passenger cars and light-duty trucks only).	SP34E	Unacceptable as of MY 2017.	This blend has a relatively high GWP of approximately 1,410. Other substitutes are available for this end-use with lower overall risk to human health and the environment.
Motor vehicle air conditioning (new equipment in passenger cars and light-duty trucks only).	R-426A (RS-24, new formulation).	Unacceptable as of MY 2017.	This blend has a relatively high GWP of approximately 1,510. Other substitutes are available for this end-use with lower overall risk to human health and the environment.

TABLE 4—FOAM BLOWING AGENTS—SUBSTITUTES ACCEPTABLE SUBJECT TO NARROWED USE LIMITS

End-use	Substitute	Decision	Narrowed use limits	Further information
Rigid Polyurethane: Appliance.	HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6.	Acceptable Subject to Narrowed Use Limits.	Acceptable until January 1, 2022 only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of: • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or • Anticipated date other substitutes will be available and projected time for switching.

TABLE 4—FOAM BLOWING AGENTS—SUBSTITUTES ACCEPTABLE SUBJECT TO NARROWED USE LIMITS—Continued

End-use	Substitute	Decision	Narrowed use limits	Further information
Rigid Polyurethane: Spray.	HFC–134a and Formacel TI.	Acceptable Subject to Narrowed Use Limits.	Acceptable until January 1, 2022 only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of: • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or • Anticipated date other substitutes will be available and projected time for switching.
Rigid Polyurethane: Commercial Refrigeration and Sandwich Panels.	HFC–134a, HFC–245fa, HFC–365mfc, and blends thereof; Formacel TI, and Formacel Z–6.	Acceptable Subject to Narrowed Use Limits.	Acceptable until January 1, 2022 only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of: • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or • Anticipated date other substitutes will be available and projected time for switching.
Flexible Polyurethane.	HFC–134a, HFC–245fa, HFC–365mfc, and blends thereof.	Acceptable Subject to Narrowed Use Limits.	Acceptable until January 1, 2022 only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of: • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or • Anticipated date other substitutes will be available and projected time for switching.
Rigid Polyurethane: Slabstock and Other.	HFC–134a, HFC–245fa, HFC–365mfc and blends thereof; Formacel TI, and Formacel Z–6.	Acceptable Subject to Narrowed Use Limits.	Acceptable until January 1, 2022 only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of: • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or • Anticipated date other substitutes will be available and projected time for switching.
Rigid Polyurethane and Polyisocyanurate Laminated Boardstock.	HFC–134a, HFC–245fa, HFC–365mfc and blends thereof.	Acceptable Subject to Narrowed Use Limits.	Acceptable until January 1, 2022 only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of: • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or • Anticipated date other substitutes will be available and projected time for switching.

TABLE 4—FOAM BLOWING AGENTS—SUBSTITUTES ACCEPTABLE SUBJECT TO NARROWED USE LIMITS—Continued

End-use	Substitute	Decision	Narrowed use limits	Further information
Polystyrene: Extruded Sheet.	HFC–134a, HFC–245fa, HFC–365mfc, and blends thereof, Formacel TI, and Formacel Z–6.	Acceptable Subject to Narrowed Use Limits.	Acceptable until January 1, 2022 only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of: • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or • Anticipated date other substitutes will be available and projected time for switching.
Polystyrene: Extruded Boardstock and Billet.	HFC–134a, HFC–245fa, HFC–365mfc, and blends thereof, Formacel B, and Formacel Z–6.	Acceptable Subject to Narrowed Use Limits.	Acceptable until January 1, 2022 only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of: • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or • Anticipated date other substitutes will be available and projected time for switching.
Integral Skin Polyurethane.	HFC–134a, HFC–245fa, HFC–365mfc, and blends thereof; Formacel TI, and Formacel Z–6.	Acceptable Subject to Narrowed Use Limits.	Acceptable until January 1, 2022 only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of: • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or • Anticipated date other substitutes will be available and projected time for switching.
Polyolefin	HFC–134a, HFC–245fa, HFC–365mfc, and blends thereof; Formacel TI, and Formacel Z–6.	Acceptable Subject to Narrowed Use Limits.	Acceptable until January 1, 2022 only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of: • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or • Anticipated date other substitutes will be available and projected time for switching.
Phenolic Insulation Board and Bunstock.	HFC–143a, HFC–134a, HFC–245fa, HFC–365mfc, and blends thereof.	Acceptable Subject to Narrowed Use Limits.	Acceptable until January 1, 2022 only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of: • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or • Anticipated date other substitutes will be available and projected time for switching.

TABLE 5—UNACCEPTABLE SUBSTITUTES

End-use	Substitute	Decision	Further Information
All	Blends of HCFC–141b	Unacceptable effective [DATE 60 DAYS AFTER PUBLICATION OF FINAL RULE].	HCFC–141b has an ozone depletion potential of 0.11 under the Montreal Protocol. EPA previously found HCFC–141b unacceptable in all foam blowing end-uses (appendix M to subpart G of 40 CFR part 82). HCFC–141b has an ODP of 0.11.

TABLE 5—UNACCEPTABLE SUBSTITUTES—Continued

End-use	Substitute	Decision	Further Information
Polyolefin	HCFC–22, HCFC–142b, and blends thereof.	Unacceptable effective [DATE 60 DAYS AFTER PUBLICATION OF FINAL RULE].	Use or introduction into interstate commerce of virgin HCFC–22 and HCFC–142b for foam blowing is prohibited after January 1, 2010 under EPA's regulations at 40 CFR part 82 subpart A unless used, recovered, and recycled. These compounds have ozone depletion potentials of 0.055 and 0.065 respectively under the Montreal Protocol.
Rigid Polyurethane: Appli- ance.	HFC–134a, HFC–245fa, HFC–365mfc and blends thereof; Formacel TI, and Formacel Z–6.	Unacceptable as of January 1, 2017 except where allowed under a narrowed use limit.	Other substitutes are available for this end-use with lower overall risk to human health and the environment, including lower GWP.
Rigid Polyurethane: Spray ...	HFC–134a and Formacel TI.	Unacceptable as of January 1, 2017 except where allowed under a narrowed use limit.	Other substitutes are available for this end-use with lower overall risk to human health and the environment, including lower GWP.
Rigid Polyurethane: Com- mercial Refrigeration and Sandwich Panels.	HFC–134a, HFC–245fa, HFC–365mfc, and blends thereof; Formacel TI, and Formacel Z–6.	Unacceptable as of January 1, 2017 except where allowed under a narrowed use limit.	Other substitutes are available for this end-use with lower overall risk to human health and the environment, including lower GWP.
Flexible Polyurethane	HFC–134a, HFC–245fa, HFC–365mfc, and blends thereof.	Unacceptable as of January 1, 2017 except where allowed under a narrowed use limit.	Other substitutes are available for this end-use with lower overall risk to human health and the environment, including lower GWP.
Rigid Polyurethane: Slabstock and Other.	HFC–134a, HFC–245fa, HFC–365mfc and blends thereof; Formacel TI, and Formacel Z–6.	Unacceptable as of January 1, 2017 except where allowed under a narrowed use limit.	Other substitutes are available for this end-use with lower overall risk to human health and the environment, including lower GWP.
Rigid Polyurethane and Polyisocyanurate Lami- nated Boardstock.	HFC–134a, HFC–245fa, HFC–365mfc and blends thereof.	Unacceptable as of January 1, 2017 except where allowed under a narrowed use limit.	Other substitutes are available for this end-use with lower overall risk to human health and the environment, including lower GWP.
Polystyrene: Extruded Sheet	HFC–134a, HFC–245fa, HFC–365mfc, and blends thereof, Formacel TI, and Formacel Z–6.	Unacceptable as of January 1, 2017 except where allowed under a narrowed use limit.	Other substitutes are available for this end-use with lower overall risk to human health and the environment, including lower GWP.
Polystyrene: Extruded Boardstock and Billet.	HFC–134a, HFC–245fa, HFC–365mfc, and blends thereof, Formacel B, and Formacel Z–6.	Unacceptable as of January 1, 2017 except where allowed under a narrowed use limit.	Other substitutes are available for this end-use with lower overall risk to human health and the environment, including lower GWP.
Integral Skin Polyurethane ..	HFC–134a, HFC–245fa, HFC–365mfc, and blends thereof; Formacel TI, and Formacel Z–6.	Unacceptable as of January 1, 2017 except where allowed under a narrowed use limit.	Other substitutes are available for this end-use with lower overall risk to human health and the environment. Other substitutes are available for this end-use with lower overall risk to human health and the environment, including lower GWP.
Polyolefin	HFC–134a, HFC–245fa, HFC–365mfc, and blends thereof; Formacel TI, and Formacel Z–6.	Unacceptable as of January 1, 2017 except where allowed under a narrowed use limit.	Other substitutes are available for this end-use with lower overall risk to human health and the environment. Other substitutes are available for this end-use with lower overall risk to human health and the environment, including lower GWP.
Phenolic Insulation Board and Bunstock.	HFC–143a, HFC–134a, HFC–245fa, HFC–365mfc, and blends thereof.	Unacceptable as of January 1, 2017 except where allowed under a narrowed use limit.	Other substitutes are available for this end-use with lower overall risk to human health and the environment, including GWP.

TABLE 6—FIRE SUPPRESSION AND EXPLOSION PROTECTION AGENTS—UNACCEPTABLE SUBSTITUTES

End-use	Substitute	Decision	Further information
Total Flooding	HCFC–22	Unacceptable effective [DATE 60 DAYS AFTER PUBLICATION OF FINAL RULE].	Use or introduction into interstate commerce of virgin HCFC–22 for total flooding fire suppression and explosion protection is prohibited as of January 1, 2010 under EPA's regulations at 40 CFR part 82 subpart A. This chemical has an ozone depletion potential of 0.055.

TABLE 7—STERILANTS—UNACCEPTABLE SUBSTITUTES

End-use	Substitute	Decision	Further information
Sterilants	Blends containing HCFC-22.	Unacceptable effective [DATE 60 DAYS AFTER PUBLICATION OF FINAL RULE].	Use or introduction into interstate commerce of virgin HCFC-22 for sterilants is prohibited as of January 1, 2010 under EPA's regulations at 40 CFR part 82 subpart A. HCFC-22 has an ozone depletion potential of 0.055.

TABLE 8—ADHESIVES, COATINGS AND INKS—UNACCEPTABLE SUBSTITUTES

End-use	Substitute	Decision	Further information
Adhesives, coatings and inks.	HCFC-141b and blends thereof.	Unacceptable effective [DATE 60 DAYS AFTER PUBLICATION OF FINAL RULE].	Use or introduction into interstate commerce of virgin HCFC-141b for adhesives, coatings and inks is prohibited as of January 1, 2015 under EPA's regulations at 40 CFR part 82 subpart A. This chemical has an ozone depletion potential of 0.11.

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