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WHEN: Tuesday, May 14, 2013
9 a.m.–12:30 p.m.

WHERE: Office of the Federal Register
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Washington, DC 20002

RESERVATIONS: (202) 741–6008

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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.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

FARM CREDIT ADMINISTRATION

12 CFR Part 615

RIN 3052–AC54

Funding and Fiscal Affairs, Loan Policies and Operations, and Funding Operations; Liquidity and Funding; Correction

AGENCY: Farm Credit Administration.

ACTION: Final rule; correction.

SUMMARY: The Farm Credit Administration (FCA) published a final rule in the **Federal Register** on April 18, 2013 to strengthen liquidity risk management at Farm Credit System (System) banks, improve the quality of assets in their liquidity reserves, and bolster the ability of System banks to fund their obligations and continue operations during times of economic, financial, or market adversity. This document corrects that rule by replacing a term that was inadvertently used.

DATES: *Effective Date:* This regulation will be effective 30 days after publication in the **Federal Register** during which either or both Houses of Congress are in session. We will publish a notice of the effective date in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: David Lewandrowski, Senior Policy Analyst, Office of Regulatory Policy, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA, (703) 883–4498, TTY (703) 883–4056; or Richard A. Katz, Senior Counsel, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TTY (703) 883–4056.

SUPPLEMENTARY INFORMATION: The FCA published a document in the **Federal Register** on April 18, 2013, (78 FR 23438) amending part 615. In FR Doc. 2013–09166, make the following corrections on two separate pages.

■ 1. Remove the term ''book'' and add in its place, the term ''market'' on page 23453, in the first column, line 18.

§ 615.5134 [Corrected]

■ 2. On page 23456, in the first column, line 4, in § 615.5134(e), remove the term ''book'' and add in its place, the term ''market''.

Dated: May 1, 2013.

Dale L. Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2013–10820 Filed 5–7–13; 8:45 am]

BILLING CODE 6705–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–369]

Schedules of Controlled Substances: Placement of Lorcaserin Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Administrator of the Drug Enforcement Administration (DEA) places the substance lorcaserin, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into Schedule IV of the Controlled Substances Act (CSA). This action is pursuant to the CSA which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking.

DATES: *Effective Date:* June 7, 2013.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone, (202) 307–7165.

SUPPLEMENTARY INFORMATION:

Legal Authority

The DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act and the Controlled Substances Import and Export Act (21 U.S.C. 801–971), as amended (hereinafter, ''CSA''). The implementing regulations for these statutes are found in Title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. Under the CSA, controlled substances are classified in one of five schedules based upon their potential for abuse, their currently accepted medical use, and the degree of dependence the substance may cause, 21 U.S.C. 812. The initial schedules of controlled substances by statute are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR Part 1308.

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, ''add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed . . .'' Pursuant to 28 CFR 0.100(b), the Attorney General has delegated this scheduling authority to the Administrator of DEA.

The CSA provides that scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS),[1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action is based on a recommendation from the Assistant Secretary of HHS and on an evaluation of all other relevant data by DEA. This action imposes the regulatory controls and criminal sanctions of Schedule IV on the manufacture, distribution, dispensing, importation, and exportation of lorcaserin and products containing lorcaserin.

Background

Lorcaserin ((*R*)–8–chloro–1–methyl–2,3,4,5–tetrahydro–1*H*–3–benzepine hydrochloride hemihydrate) is a new

[1] As set forth in a memorandum of understanding entered into by HHS, the Food and Drug Administration, (FDA), and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518. In addition, because the Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations, for purposes of this document, all subsequent references to ''Secretary'' have been replaced with ''Assistant Secretary.''

chemical entity which has central nervous system hallucinogenic properties. Lorcaserin is a serotonin receptor agonist, at the $5HT_{2C}$ and $5HT_{2A}$ receptor subtypes. Lorcaserin HCl was approved by the Food and Drug Administration (FDA) on June 27, 2012, as an addition to a reduced-calorie diet and exercise, for chronic weight management and it will be marketed under the trade name BELVIQ®.

HHS and DEA Eight-Factor Analyses

On June 25, 2012, the Department of Human Health Service (HHS) provided to the Drug Enforcement Administration (DEA) a scientific and medical evaluation and scheduling recommendation entitled ''Basis for the Recommendation for Control of Lorcaserin in Schedule IV of the Controlled Substances Act.'' Following consideration of the eight factors and findings related to the substance's abuse potential, legitimate medical use, and dependence liability, HHS recommended that lorcaserin be controlled in Schedule IV of the CSA under 21 U.S.C. 812 (b).

In response, DEA conducted an eight-factor analysis of abuse potential of lorcaserin pursuant to 21 U.S.C. 811(c).

Determination to Schedule Lorcaserin

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from HHS, the Administrator of the DEA published in the **Federal Register** a Notice of Proposed Rulemaking (NPRM) entitled, ''Schedules of Controlled Substances: Placement of Lorcaserin into Schedule IV'' on December 19, 2012 (77 FR 75075), which proposed placement of lorcaserin into Schedule IV of the CSA. The proposed rule provided an opportunity for all interested persons to submit their written comments on or before January 18, 2013.

Comments Received

DEA received seventy-one comments on the proposed rule to schedule lorcaserin. Commenters included individual health-care providers, national organizations, shareholders in the company which will market BELVIQ®, consultants, medical researchers, and other concerned citizens. There were 16 commenters in favor of the proposed rule and one opposed to it, with the remaining 54 commenters not taking a position.

Support of the Proposed Rule

Fifteen commenters supported controlling lorcaserin as a Schedule IV substance. Eleven commenters indicated support for controlling lorcaserin under the CSA based on the abuse potential of the substance. Most of the commenters supported the proposal to control lorcaserin as a Schedule IV substance. Because lorcaserin will be indicated as a weight loss drug, some commenters mentioned that there will be a high demand for the drug by the general public upon the drug being marketed. According to the commenters, controlling lorcaserin as a Schedule IV substance will therefore provide the necessary controls to prevent its diversion. Two commenters mentioned that weight loss drugs are needed in the United States.

DEA Response: DEA appreciates the support for this rulemaking.

Opposition to the Proposed Rule

Two commenters opposed the proposal to control lorcaserin as a Schedule IV substance. One commenter stated that lorcaserin should be controlled as a Schedule V substance, based on the commenter's stance that DEA is making assumptions of the abuse potential of lorcaserin. The commenter indicated that DEA did not include the methodology used to determine the abuse potential of lorcaserin. The other commenter stated that lorcaserin should be a non-controlled substance based on data from a published study on the abuse potential of lorcaserin in recreational polydrug users.[2]

DEA Response: DEA does not agree. The studies used to assess abuse potential of lorcaserin are widely held as the standard methods of evaluation. Clinical studies indicated that lorcaserin, similar to comparator drugs zolpidem (Schedule IV) and ketamine (Schedule III) produced significant increases on positive subjective measures (VAS for ''high'' and ''good drug effects'') as well as an increase on the VAS for ''hallucinations.'' Lorcaserin, as well as zolpidem and ketamine, significantly increased reports of ''sedation'' on the subjective scale of the ARCI, compared to placebo. In a human abuse potential study, incidence of euphoria resulting from lorcaserin administration is similar to the incidence reported following zolpidem (Schedule IV) administration (13–16%) and lower than that following ketamine (Schedule III) administration (50%). The DEA did consider in its evaluation the published article [1] cited by the commenter. The data collectively suggest that lorcaserin does have sufficient abuse potential to warrant control under the CSA. HHS recommended control of lorcaserin in Schedule IV of the CSA and the DEA's placement findings support this level of control.

Requests To Control Lorcaserin in a Higher Schedule Than Schedule IV

Four commenters expressed concern that Schedule IV was not a stringent enough schedule for lorcaserin, based on it being an agonist at the $5–HT_{2A}$ receptors. These commenters suggested that lorcaserin be controlled in Schedule II or Schedule III. $5–HT_{2A}$ receptors mediate hallucinogenic properties of other drugs, such as lysergic acid diethylamide (LSD).

DEA Response: DEA believes that placement in Schedule IV of the CSA will help restrict unsafe access to lorcaserin and reduce instances of its abuse. Upon receiving from HHS a scientific and medical evaluation and a scheduling recommendation for lorcaserin, DEA also conducted its own analysis of the eight factors in accordance with 21 U.S.C. 811(b). Based on the review of HHS' evaluation and scheduling recommendation and other relevant data, DEA found that lorcaserin had a low potential for abuse relative to ketamine, a Schedule III drug, a currently accepted medical use for treatment in the United States, and that abuse of lorcaserin may lead to limited physical or psychological dependence relative to drugs in Schedule III. On the basis of these findings, lorcaserin is appropriately being controlled in Schedule IV.

Requests To Expedite the Lorcaserin Scheduling Action

There were thirty-two comments which requested that DEA expedite the scheduling action for lorcaserin. Generally, the commenters indicated that the scheduling action should be expedited due to epidemic levels of obesity in the United States and the absence of any weight loss drugs on the market with lorcaserin's novel mechanism of action. Some commenters stated that the review conducted by FDA was sufficient to justify that lorcaserin be controlled expeditiously. Of these thirty-two comments, seven comments also requested that, ''in the interest of public health,'' DEA waive the 30-day comment or implementation period in order to make lorcaserin available immediately. One commenter stated that the scheduling action should be expedited because ''based on scientific evidence that is available to date, there is no risk of this drug being addictive, and therefore abused.''

From the previously mentioned thirty-two comments, eight comments

[2] Shram et al. (2011) Clin Pharmacol Ther; 89(5):683–92.

requested that the placement of lorcaserin in Schedule IV become effective on the date of the publication of the Final Rule. One commenter requested that the implementation period be limited to two weeks instead of the standard 30 days. Generally the commenters stated that since obesity and obesity-related illnesses are occurring at epidemic levels, lorcaserin should be available to health care practitioners and patients in the immediate future. One commenter referenced other scheduling actions in which the effective date was the same as the publication date of the Final Rule as justification of doing the same for the lorcaserin. The scheduling actions referenced were zopiclone (70 FR 16935), pregabalin (70 FR 43633), and ezogabine (76 FR 77895).

DEA Response: DEA believes that providing 30 days for this rule to become effective is both expeditious and sufficient to allow handlers to apply for registration with DEA and to comply with regulatory requirements for handling Schedule IV controlled substances. With regard to the comment about lack of abuse potential for lorcaserin, as mentioned in both HHS' and DEA's scientific and medical analyses, the data collectively suggest that lorcaserin does have sufficient abuse potential and though the effective dates for scheduling zopiclone, pregabalin, and ezogabine were the date of publication of their respective Final Rule, DEA does not agree that lorcaserin's effective date should be the date of publication of the Final Rule. The clinical indications of above referenced drugs are different from that of lorcaserin. DEA believes that the clinical indications for lorcaserin do not support the waiver of the 30-day period. With regard to the availability of weight-loss drugs, DEA further notes that other weight-loss drugs are currently available on the market.

Phentermine Being Combined With Lorcaserin

Eight commenters expressed concern about the probability that healthcare providers would prescribe phentermine with lorcaserin to increase weight loss results in patients.

DEA Response: Prescriptions for controlled substances, including lorcaserin, must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. A determination of the validity of a prescription depends on an evaluation of the particular circumstances surrounding its issuance.

Risk Evaluations and Mitigation Strategy (REMS) Program for Lorcaserin

Three commenters stated that there should be a REMS program in place for the prescribing and dispensing of prescriptions of lorcaserin to minimize the misuse of lorcaserin. Two of these commenters also expressed concern about the effects of direct-to-consumer television advertisements of lorcaserin.

DEA Response: FDA is responsible for determining whether REMS programs should be implemented for particular drugs. Various agencies, such as FDA and the Federal Trade Commission (FTC), have a role in regulating direct-to-consumer drug advertising.

Request for a Hearing

One commenter requested a formal hearing prior to the finalization of the scheduling action for lorcaserin. The commenter expressed concern that the potential for abuse of lorcaserin is large since the indication is for the drug to be taken chronically for weight loss. The commenter requested that the hearing include ''relevant experts.''

DEA Response: DEA regulations provide that ''[a]ny interested person'' may request a hearing on a proposed scheduling action. 21 CFR 1308.44(a). DEA regulations define ''interested person'' as ''any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to [21 U.S.C. 811].'' 21 CFR 1300.01(b). The regulations further require that any person requesting a hearing must state ''with particularity'' his interest in the proceeding. 21 CFR 1316.47(a). Because the commenter failed to provide sufficient information to demonstrate that he meets the definition of ''interested person'' as set forth in the regulations, DEA hereby denies this hearing request.

Other Comments

The remaining comments were concerning various topics, not all of them being related to lorcaserin directly. The comments are summarized below as follows:

- Several commenters were critical of DEA's handling of the scheduling process. The commenters did not provide specific recommendations for action.
- One commenter expressed concern about the abuse potential of lorcaserin. The commenter did not indicate whether they opposed or supported the proposal to control lorcaserin.
- One commenter requested that DEA extend the comment period for the NPRM by 60 additional days. The commenter indicated that the public had not been given sufficient time to respond to the NPRM. DEA has allowed 30 days for a comment period in previous scheduling actions for new chemical entities. A 30-day comment period has been demonstrated to be a sufficient period to allow the public to submit comments to proposed scheduling actions.
- One commenter submitted information about Combo Pilling, which is not related to the current control action.
- One commenter discussed the side effects experienced with taking Qsymia, a weight loss drug. This comment was not related to the current scheduling action.
- Two commenters stated that obesity drugs are not needed to deal with the current obesity epidemic. This comment was not related to the current scheduling action.

Scheduling Conclusion

Based on consideration of all comments, the scientific and medical evaluation and accompanying recommendation of HHS, and based on DEA's consideration of its own eight-factor analysis, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of lorcaserin. As such, DEA will schedule lorcaserin as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as Schedules I, II, III, IV, and V. The statute outlines the findings required for placing a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all available data, the Administrator of DEA, pursuant to 21 U.S.C. 812(b)(4), finds that:

(1) Lorcaserin has a low potential for abuse relative to the drugs or other substances in Schedule III. The overall abuse potential of lorcaserin is comparable to Schedule IV substances such as zolpidem;

(2) Lorcaserin has a currently accepted medical use in treatment in the United States. Lorcaserin HCL was approved for marketing by FDA as an addition to a reduced-calorie diet and exercise, for chronic weight management; and

(3) Abuse of lorcaserin may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III. This finding is based on the ability of lorcaserin to produce positive subjective effects at supratherapeutic doses.

Based on these findings, the Administrator of DEA concludes that lorcaserin, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, warrants

control in Schedule IV of the CSA (21 U.S.C. 812(b)(4)).

Requirements for Handling Lorcaserin

Upon the effective date of this final rule, lorcaserin is subject to the CSA and the Controlled Substances Import and Export Act (CSIEA) regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, and exporting of a Schedule IV controlled substance, including the following:

Registration. Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with lorcaserin, or who desires to manufacture, distribute, dispense, import, export, engage in research or conduct instructional activities with lorcaserin, must be registered to conduct such activities pursuant to 21 U.S.C. 822 and in accordance with 21 CFR Part 1301. Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration on or before June 7, 2013 and may not continue their activities until DEA has approved that application.

Security. Lorcaserin is subject to Schedules III–V security requirements and must be manufactured, distributed, and stored pursuant to 21 U.S.C. 823 and in accordance with 21 CFR 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76, and 1301.77 on or after June 7, 2013.

Labeling and Packaging. All labels and labeling for commercial containers of lorcaserin must be in accordance with 21 CFR 1302.03–1302.07, pursuant to 21 U.S.C. 825, on or after June 7, 2013.

Inventory. Every registrant required to keep records and who possesses any quantity of lorcaserin must keep an inventory of all stocks of lorcaserin on hand pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, 1304.06, and 1304.11 on or after June 7, 2013. Every registrant who desires registration in Schedule IV for lorcaserin is required to conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants must keep records pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 on or after June 7, 2013.

Prescriptions. All prescriptions for lorcaserin or prescriptions for products containing lorcaserin must comply with 21 U.S.C. 829 and 21 CFR 1306, including but not limited to 21 CFR 1306.03–1306.06, 1306.08, 1306.09, and 1306.21–1306.27 on or after June 7, 2013.

Importation and Exportation. All importation and exportation of lorcaserin must be done in accordance with 21 CFR Part 1312, pursuant to 21 U.S.C. 952, 953, 957, and 958, on or after June 7, 2013.

Criminal Liability. Any activity with lorcaserin not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act shall be unlawful on or after June 7, 2013.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget pursuant to Section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the states, on the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This rule does not have tribal implications warranting the application of Executive Order 13175. 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.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. The purpose of this final rule is to place lorcaserin, including its salts, isomers and salts of isomers, into Schedule IV of the CSA. By this final rule, lorcaserin will remain in Schedule IV unless and until additional scheduling action is taken to either transfer it between the schedules or to remove it from the list of schedules. See 21 U.S.C. 811 and 812. No less restrictive measures (i.e., non-control) enable DEA to meet its statutory obligations under the CSA.

Lorcaserin is a new chemical entity and is not currently available or marketed in any country. According to publicly available information reviewed by DEA, lorcaserin is anticipated to enjoy patent protection for at least a decade before generic equivalents may be manufactured and marketed. Accordingly, the number of currently identifiable manufacturers, importers, and distributors for lorcaserin is extremely small. The publicly available materials also specify the readily identifiable persons subject to direct regulation by this final rule. Based on guidelines utilized by the Small Business Administration, the lorcaserin manufacturer was identified as a small entity and is expected to conduct manufacturing activities at a facility outside the United States; the distributor/importer does not meet the standard as a small entity. Once generic equivalents are developed and approved for manufacturing and marketing, there may be additional manufacturers, importers, and distributors of lorcaserin, but whether they may qualify as small entity cannot be determined at this time.

There are approximately 1.4 million controlled substance registrants, approximately 381,000 of which are estimated to be businesses. DEA estimates that 371,000 (97%) of these businesses are considered ''small entities'' in accordance with the RFA and Small Business Administration standards. 5 U.S.C. 601(6) and 15 U.S.C. 632. However, due to the wide variety of unidentifiable and unquantifiable variables that potentially could influence the dispensing rates of new chemical entities, DEA is unable to determine the number of small entities which might dispense (including administer or prescribe) lorcaserin (e.g., pharmacies and prescribers).

Despite the fact that the number of small businesses possibly impacted by this rule could not be determined, DEA concludes that they would not experience a significant economic impact as a result of this rule. Currently

98% of DEA registrants (most of which are small businesses) are authorized to handle Schedule IV controlled substances. Even if we assume that all of these registrants were to handle lorcaserin (e.g., practitioners prescribe the substance, and pharmacies dispense those prescriptions), the costs that they would incur as a result of lorcaserin's scheduling would be nominal. Registrants that dispense (but not prescribe) would incur nominal additional security, inventory, recordkeeping, and labeling costs. These registered entities have already established and implemented these systems and processes required to handle Schedule IV controlled substances, and can easily absorb the costs of dispensing lorcaserin with nominal to no additional economic burden. For example, pharmacies and institutional practitioners may disperse Schedule II through V controlled substances throughout the stock of noncontrolled substances in such a manner as to obstruct theft or diversion of the controlled substances. In addition, because registered pharmacies must label all Schedule II through V controlled substances that they dispense, the requirement to label all dispensed substances containing lorcaserin would not impose a significant economic burden upon registered pharmacies. Accordingly, compliance would not require significant additional manpower, capital investment, or recordkeeping burdens.

The only additional requirement imposed by this rule upon registrants that only prescribe substances containing lorcaserin is that they issue an oral or written prescription to dispense the substance. Accordingly, registered prescribers would not incur any additional security, inventory, recordkeeping, or labeling costs as a result of this rule as they would not physically handle lorcaserin.

Because of these facts, this rule will not result in a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

For the reasons stated in the above section titled, ''Regulatory Flexibility Act,'' [3] this rule does not include a Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995 (UMRA).

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521.

Congressional Review Act

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in: an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and export markets. However, pursuant to the CRA, DEA has submitted a copy of this Final Rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

Under the authority vested in the Attorney General by Section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.100) the Administrator hereby amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

The authority citation for 21 CFR Part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 1. Section 1308.14 is amended by redesignating paragraphs (e) and (f) as paragraphs (f) and (g), and adding a new paragraph (e) to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(e) *Lorcaserin.* Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:

(1) Lorcaserin 1625

* * * * *

Dated: April 29, 2013.

Michele M. Leonhart,

Administrator.

[FR Doc. 2013–10895 Filed 5–7–13; 8:45 am]

BILLING CODE 4410–09–P

[3] UMRA and the RFA share the same definition of ''rule.'' UMRA defines ''regulation'' or ''rule'' by cross-referencing the RFA's definition of ''rule.'' 2 U.S.C. 658(10)). The RFA generally defines ''rule'' as ''any rule for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b) of [the Administrative Procedure Act].'' 5 U.S.C. 601(2).

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket Nos. 09–197; 11–42; FCC 13–44]

Telecommunications Carriers Eligible for Support; Lifeline and Link Up Reform and Several Petitions for Forbearance

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this order, the Federal Communications Commission (Commission) grants limited forbearance from the requirement of the Commission's rules that the service area of an eligible telecommunications carrier (ETC) conform to the service area of any rural telephone company serving the same area. In particular, this grant of forbearance applies to any ETC that has been designated by a state or the Commission, as well as pending and future requests by telecommunications carriers that seek limited designation, as an ETC to participate only in the Lifeline program (Lifeline-only ETC). The Commission concludes that forbearance furthers the Act's and Commission's goals of ensuring the availability of voice service to low-income consumers.

DATES: Effective June 7, 2013, except paragraph 19 which is effective upon release of the Memorandum Opinion and Order.

FOR FURTHER INFORMATION CONTACT: Alexander Minard, Wireline Competition Bureau, (202) 418–0428 or TTY: (202) 418–0484.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Memorandum Opinion and Order (Order) in WC Docket Nos. 09–197;11–42; FCC 13–44, released on April 15, 2013. The full text of this document 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/2013/db0415/FCC–13–44A1.pdf.

I. Introduction

1. In this Order, pursuant to section 10 of the Communications Act of 1934, as amended (the Act), we grant limited forbearance from the requirement of section 214(e)(5) of the Act and § 54.207(b) of the Commission's rules that the service area of an eligible telecommunications carrier (ETC) conform to the service area of any rural telephone company serving the same area. In particular, this grant of forbearance applies to any ETC that has been designated by a state or the Commission, as well as pending and future requests by telecommunications carriers that seek limited designation, as an ETC to participate only in the Lifeline program (Lifeline-only ETC).

2. We conclude that forbearance furthers the Act's and Commission's goals of ensuring the availability of voice service to low-income consumers. Moreover, we find that application of the conformance requirements set forth in section 214(e)(5) of the Act and § 54.207(b) of the Commission's rules is not necessary to ensure that rates remain just and reasonable or to protect consumers. We emphasize that the forbearance granted herein is limited to a carrier's designation as a Lifeline-only ETC. If any carrier petitions to become an ETC to receive high-cost support, this forbearance order is inapplicable and such carrier must satisfy all of the statutory requirements applicable to ETCs under the Act.

II. Discussion

3. We conclude that forbearing from the conformance requirement of section 214(e)(5) of the Act and § 54.207(b) of the Commission's rules is appropriate and in the public interest for carriers seeking designation, or already designated, as Lifeline-only ETCs. For the reasons explained below, we find that all three prongs of section 10(a) are satisfied. As a result, if a commission designates a carrier as a limited, Lifeline-only ETC in part of a rural service area, that designation will not require redefinition of the rural telephone company's service area. Because forbearance would apply only to designations for the purpose of becoming a limited ETC to participate in the Commission's Lifeline program, we examine the conformance requirement in light of the statutory goal of providing low-income consumers with access to telecommunications services as it relates to the Commission's Lifeline program.

4. Given that designating authorities may have already designated carriers as Lifeline-only ETCs in partial rural service areas without seeking redefinition, the Commission will not enforce the conformance requirement for those previously granted ETC designations. Such ETCs need not amend their service area and may rely on this forbearance to continue serving partial rural service areas. If the designating authority required Lifeline-only ETCs to follow the conformance requirement in its designation, the ETCs must abide by its designation order. We emphasize, however, that if any carrier seeks designation to be an ETC to receive high-cost support in part of a service area served by a rural telephone company, we do not forbear from the redefinition process that is required by the Act.

5. *Just and Reasonable.* Section 10(a)(1) of the Act requires that we consider whether enforcement of the provisions from which forbearance is sought is necessary to ensure that the charges, practices, classifications, or regulations by, for, or in connection with the carriers or services at issue are just and reasonable and not unjustly or unreasonably discriminatory. We conclude that compliance with the conformance requirement of section 214(e)(5) of the Act and § 54.207(b) of the Commission's rules is not necessary to ensure that a Lifeline-only carrier's charges, practices, and classifications are just and reasonable and not unjustly or unreasonably discriminatory where it is providing Lifeline service only. Lifeline support, designed to reduce the monthly cost of telecommunications services for eligible consumers, is distributed on a per-subscriber basis and is directly reflected in the price that the eligible subscriber pays. As discussed below, we find that the factors traditionally taken into account by the Commission and the states when reviewing a potential redefinition of a rural service area pursuant to section 214(e)(5) of the Act do not apply in the context of conditionally designating ETCs in areas eligible for Lifeline support. Furthermore, forbearance from the service area conformance requirement would not prevent the Commission from enforcing sections 201 or 202 of the Act, which require all carriers to charge just, reasonable, and non-discriminatory rates. The Lifeline offerings of carriers subject to this forbearance will compete, at a minimum, with the Lifeline offerings of the incumbent wireline carrier, as well as other wireline and wireless providers, in any given geographic area. We also expect that this competition will spur innovation among carriers in their Lifeline offerings, expanding the choice of Lifeline products for eligible consumers. The resulting competition is likely to help ensure just, reasonable, and nondiscriminatory offerings of services. For these reasons, we find that the first prong of section 10(a) is met.

6. *Consumer Protection.* Section 10(a)(2) requires that we consider whether applying the conformance requirement to a voice service provider that has previously received designation, or will seek a Lifeline-only ETC designation through a pending designation request or at some time in the future, is necessary for the protection of consumers. Carriers designated as Lifeline-only ETCs offer Lifeline-eligible consumers an additional choice of providers for discounted telecommunications services. Forbearance from the conformance requirement for Lifeline-only support may provide additional competitive choices to many low-income consumers who cannot afford non-discounted offerings. Moreover, there is no evidence that forbearance from the conformance requirement for the limited purpose of being a Lifeline-only ETC would harm consumers currently served by the rural telephone companies in the relevant service areas. Finally, every ETC, including any carrier receiving Lifeline-only support, must certify that it will satisfy applicable consumer protection and service quality standards in its service area. For these reasons, we find that the second prong of section 10(a) is met.

7. *Public Interest.* Section 10(a)(3) requires that we consider whether forbearing from the conformance requirement to carriers that have previously received designation, have pending designation requests or will seek ETC designation for Lifeline support only in the future is in the public interest. We find that forbearance from the service area conformance requirement in these limited circumstances will promote competitive market conditions for the Lifeline program. Requiring carriers to conform their service areas to those of the rural carriers in the states they seek to participate only in the Lifeline program could result in numerous redefinition proceedings, which could delay their entry into those markets, make it more difficult to market to potential Lifeline consumers on a statewide basis, and deprive low-income consumers in areas where the incumbent wireline provider is a rural telephone company of an additional choice of service provider. For example, carriers state that the

redefinition process for Lifeline-only offerings may take years to resolve and, as such, wastes resources of both carriers and regulators. Additionally, to avoid disruption of service to low-income consumers served by existing Lifeline-only ETCs that were previously designated by state designating authorities or the Commission that defined carriers' service areas as part of a rural service area in its original ETC designation, those ETCs need not amend their service areas and may rely on this forbearance to continue serving partial rural service areas. We find that applying the conformance requirement to Lifeline-only ETCs would not be in the public interest when balanced against the benefits of maintaining or introducing a competitive alternative Lifeline provider to low-income consumers.

8. We disagree with assertions that granting forbearance from the conformance requirement for Lifeline-only ETC designation will have a detrimental effect on rural telephone companies. In response to the Cox Petition, the Atlas Telephone Company expresses concerns that granting forbearance from the conformance requirement and redefinition process could cause a rural telephone company to suffer the same adverse effects from losing customers to other Lifeline providers, as observed under traditional creamskimming analysis, specifically arguing that as a rural telephone company's low-income consumers migrate to other Lifeline providers, the number of lines served by the rural telephone company declines, causing its cost per line to increase. As the Commission previously explained, the amount of Lifeline support is not tied to the cost of serving an area. Rather, Lifeline support is a fixed, per-line amount nationwide, and ETCs are required to pass through the Lifeline support they receive to the benefit of their subscribers. Any creamskimming concerns in an area of a rural telephone company are not relevant in considering the designation of a Lifeline-only ETC. Creamskimming is not a public-interest consideration in the Lifeline context, whether the competing carrier is offering wireline or wireless service. We find that the Act contains safeguards to address any concerns raised by Atlas or any other rural telephone company that questions whether the designation of a carrier as a Lifeline-only ETC is in the public interest. The Act already requires designating commissions to affirmatively determine that designating a carrier as an ETC within a rural service area is in the public interest and that determination is not affected by this grant of forbearance. As a result, any concerns raised by a rural telephone company will be evaluated by the designating authority when considering designating a limited, Lifeline-only ETC.

9. We also disagree with the argument that granting forbearance from the conformance requirement will eliminate the role of states in ETC designations and redefinition. Forbearance in these limited circumstances merely removes the conformance requirement for previously designated ETCs receiving Lifeline-only support and carriers with pending or future ETC designation requests for Lifeline-only support, so that states, which have jurisdiction over most ETCs, may now designate Lifeline-only ETCs in a portion of a rural service area without requiring redefinition of that rural service area. State commissions are still required to consider the public interest, convenience and necessity of designating carriers as a competitive ETC in a rural area already served by a rural telephone company. Our decision here to grant forbearance for Lifeline-only designations does not disturb the roles of state commissions and this Commission in the ETC designation process or in the redefinition process in other circumstances when redefinition is required.

10. For pending and future Lifeline-only designation requests, carriers' service area will no longer be required to conform to the service area of the rural telephone companies serving the same area. The Commission recognizes all of the important issues raised by commenters in determining whether a particular carrier has met the requirements to become an ETC for the limited purpose of receiving Lifeline support, all of which will be addressed by the designating authority when a carrier submits an application requesting designation. Designating authorities will continue to make an independent assessment as to whether designating a carrier as an ETC within a rural service area is in the public interest.

11. Our decision here to forbear from the service area conformance requirement does not affect the findings of any prior ETC designation. Virgin Mobile, i-wireless, Q Link and Global Connection seek forbearance with respect to those areas previously designated by state designating agencies and the Commission. For previously designated Lifeline-only ETCs serving partial rural areas, the designating authorities have already determined that designating such carriers as ETCs is in the public interest. Any carrier that has already been designated as an ETC must comply with the obligations of their ETC designation orders.

12. The Commission has made clear its commitment to improve accountability for providers receiving universal service support in its continued effort to fight waste, fraud, and abuse. In the Commission's prior grant of forbearance from the service area conformance requirement, it conditioned forbearance on the carriers submitting, and having the Wireline Competition Bureau approve, a plan to comply with several obligations imposed in that order before it could begin providing service in accordance with its grant of forbearance. The Commission has since adopted numerous conditions in the *Lifeline Reform Order, 77 FR 12952, March 2, 2012,* to reduce waste, fraud and abuse in the Lifeline program, and thus, eliminated the need to impose additional conditions in the context of forbearance from the service area conformance requirement. Although carriers may now be designated a Lifeline-only ETC by either a state commission or this Commission in partial rural service areas, no carrier seeking to avail itself of this limited forbearance grant may be designated in a part of a rural service area to receive federal high-cost support without first seeking redefinition of the underlying rural telephone company's study area.

13. For the reasons stated herein, we find that the statutory requirements for forbearance pursuant to section 10 of the Act are met and that granting blanket forbearance from the conformance requirement for Lifeline-only ETC designations will further the statutory goals of providing low-income subscribers access to telecommunications and emergency services and promoting more competitive options for low-income consumers while protecting the universal service fund against waste, fraud, and abuse. We also note that state commissions and this Commission are still required to make an independent assessment as to whether granting a carrier ETC designation is in the public interest before including any part of a rural service area in such carrier's service area. Furthermore, forbearance from the conformance requirement stated herein does not apply if any carrier seeks ETC designation to receive high-cost support; in that instance, such carrier must conform its service area to that of the rural telephone company or else seek redefinition of the service area pursuant to § 54.207 of the Commission's rules.

III. Procedural Matters

A. Paperwork Reduction Act

14. The Memorandum Opinion and Order does not contain new or modified information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002.

B. Final Regulatory Flexibility Act Certification

15. The Regulatory Flexibility Act (''RFA'') requires that agencies prepare a regulatory flexibility analysis for notice-and-comment rulemaking proceedings, unless the agency certifies that ''the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines ''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 Small Business Administration (SBA).

16. We hereby certify that the forbearance decision in this Memorandum Opinion and Order will not have a significant economic impact on a substantial number of small entities. In this Memorandum Opinion and Order, the Commission eases the regulatory compliance burden on Lifeline-only ETCs by forbearing from the requirement that the service area of a Lifeline-only ETC conform to the service area of any rural telephone company serving the same area. This Memorandum Opinion and Order does not modify any of our reporting requirements. The Commission will send a copy of this Memorandum Opinion and Order, including this certification, to the Chief Counsel for Advocacy of the SBA. In addition, the Memorandum Opinion and Order (or a summary thereof) and certification will be published in the **Federal Register**.

C. Congressional Review Act

17. The Commission will send a copy of this Memorandum Opinion and Order to Congress and the Government Accountability Office pursuant to the Congressional Review Act.

IV. Ordering Clauses

18. *It is ordered* that, pursuant to the authority contained in sections 4(i), 4(j), 10, 201, 214, and 254 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j), 160, 201, 214, 254, we forbear from applying the conformance requirement of section 214(e)(5) of the Communications Act of 1934, as amended, 47 U.S.C. 214(e)(5), and § 54.207(b) of the Commission's rules, 47 CFR 54.207(b), to the extent discussed herein.

19. *It is further ordered* that, pursuant to the authority contained in sections 4(i), 4(j), 10, 201, 214, and 254 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j), 160, 201, 214, 254, the petitions for forbearance filed by Virgin Mobile USA, L.P., Cox Communications, Inc., Time Warner Cable, Inc., I-Wireless, LLC, Q Link Wireless, LLC and Global Connection Inc. of America *are granted* to the extent discussed herein, effective upon release.

20. *It is further ordered* that, except as provided in paragraph 19 above, this Order *shall be effective* June 7, 2013.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2013–10851 Filed 5–7–13; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 130123063–3423–03]

RIN 0648–BC75

Pacific Halibut Fisheries; Catch Sharing Plan; Correcting Amendment

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

ACTION: Final rule; correcting amendment.

SUMMARY: This action corrects the text of a final rule published on March 15, 2013, that implemented annual management measures governing the Pacific halibut fishery. This final rule established season dates off of Alaska, Washington, Oregon and California. This action is necessary to correct an error in the days of the week listed for the fishing season in the area from Leadbetter Point, WA to Cape Falcon, OR.

DATES: Effective May 8, 2013.

FOR FURTHER INFORMATION CONTACT: Sarah Williams, 206–526–4646.

SUPPLEMENTARY INFORMATION: A final rule published March 15, 2013 (78 FR 16423), included annual management measures for managing the harvest of Pacific halibut (*Hippoglossus stenolepis*) in the sport fishery in International Pacific Halibut Commission (IPHC) Regulatory Area 2A off of Washington, Oregon and California. This correcting amendment revises the season days of the week in the area from Leadbetter Point, WA to Cape Falcon, OR.

Need for Correction

The final rule (78 FR 16423), Section 26, Sport Fishing for Halibut Area 2A, describes dates and days of the week for sport fishing for halibut off Washington, Oregon, and California. For the area from Leadbetter Point, WA to Cape Falcon, OR the days of the week for the season from May 3 to July 28 were listed as Thursday, Friday, Saturday and should have been listed as Friday through Sunday. Friday through Sunday is consistent with the 2013 Pacific Fishery Management Council's Catch Sharing Plan which describes the structure of the fishery and the proposed rule (78 FR 9660). The incorrect days of the week were inadvertently included in the final rule. ''Thursday, Friday, Saturday'' is corrected to read ''Friday through Sunday'' in the corrected text set out below.

On page 16435, paragraph (8)(d)(i), in the third column, is corrected to read as follows:

(i) The fishing season commences on May 3, and continues 3 days a week (Friday through Sunday) until 9,516 lb (4.3 mt) are estimated to have been taken and the season is closed by the Commission or until July 28, whichever is earlier. The fishery will reopen on August 2 and continue 3 days a week (Friday through Sunday) until 2,379 lb (1.1 mt) have been taken and the season is closed by the Commission, or until September 30, whichever is earlier. Subsequent to this closure, if there is insufficient quota remaining in the Columbia River subarea for another fishing day, then any remaining quota may be transferred in-season to another Washington and/or Oregon subarea by NMFS via an update to the recreational halibut hotline. Any remaining quota would be transferred to each state in proportion to its contribution.

Classification

Pursuant to 5 U.S.C. 553(b)(B), the Acting Assistant Administrator for

Fisheries finds there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be unnecessary and contrary to public interest. Notice and comment are unnecessary and contrary to the public interest because this action corrects an inadvertent error in regulations for a fishery that commences on May 3, and immediate notice of the error and correction is necessary to prevent confusion among participants in the fishery that could result from the existing conflict between the Catch Sharing Plan and proposed rule, and the final rule. In addition, this action makes only minor changes to the dates of the fishery and does not alter the total number of days the fishery will be open. These corrections will not affect the results of analyses conducted to support management decisions in the halibut fishery nor change the total catch of halibut. No change in operating practices in the fishery is required. For the same reasons, the Acting AA has determined that good cause exists to waive the 30-day delay in effectiveness pursuant to 5 U.S.C. 553(d).

This final rule complies with the Halibut Act and the Pacific Fishery Management Council's authority to implement allocation measures for the management of the halibut fishery.

Authority: 16 U.S.C. 773 *et seq.*

Dated: May 2, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2013–10933 Filed 5–3–13; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 120306154–2241–02]

RIN 0648–XC651

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

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

ACTION: Temporary rule; inseason General category retention limit adjustment.

SUMMARY: NMFS is adjusting the Atlantic bluefin tuna (BFT) General category daily retention limit to three large medium or giant BFT for June 1 through August 31, 2013. This action is based on consideration of the regulatory determination criteria regarding inseason adjustments, and applies to Atlantic tunas General category (commercial) permitted vessels and Highly Migratory Species (HMS) Charter/Headboat category permitted vessels when fishing commercially for BFT.

DATES: Effective June 1, 2013, through August 31, 2013.

FOR FURTHER INFORMATION CONTACT: Sarah McLaughlin or Brad McHale, 978–281–9260.

SUPPLEMENTARY INFORMATION: Regulations implemented under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) among the various domestic fishing categories, per the allocations established in the 2006 Consolidated Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (71 FR 58058, October 2, 2006) and in accordance with implementing regulations. NMFS is required under ATCA and the Magnuson-Stevens Act to provide U.S. fishing vessels with a reasonable opportunity to harvest the ICCAT-recommended quota.

The 2010 ICCAT recommendation regarding western BFT management resulted in baseline U.S. quotas for 2011 and for 2012 of 923.7 mt (not including the 25 mt ICCAT allocated to the United States to account for bycatch of BFT in pelagic longline fisheries in the Northeast Distant Gear Restricted Area). The 2011 BFT quota rule (76 FR 39019, July 5, 2011) implemented the base quota of 435.1 mt for the General category fishery (a commercial tunas fishery in which handgear is used). Each of the General category time periods (January, June through August, September, October through November, and December) is allocated a portion of the annual General category quota. Although NMFS has published proposed quota specifications for 2013 (78 FR 21584, April 11, 2013), the baseline General category subquotas as codified would not be changed, including the 217.6-mt June through August General category subquota.

The 2013 BFT fishing year, which is managed on a calendar-year basis and subject to an annual calendar-year quota, began January 1, 2013. The General category season, which was open January 1 through February 15, 2013, resumes on June 1, 2013, and continues through December 31, 2013. Unless changed, the General category daily retention limit would be the default retention limit of one large medium or giant BFT (measuring 73 inches (185 cm) curved fork length (CFL) or greater) per vessel per day/trip (§ 635.23(a)(2)). This default retention limit applies to General category permitted vessels and to HMS Charter/Headboat category permitted vessels when fishing commercially for BFT.

For the 2012 fishing year, NMFS adjusted the General category limit from the default level of one large medium or giant BFT as follows: Two large medium or giant BFT for January (76 FR 76900, December 9, 2011), and three large medium or giant BFT for June through August (77 FR 28496, May 15, 2012), and three large medium or giant BFT for September through December (77 FR 53150, August 31, 2012). In December 2012, NMFS transferred 40 mt of BFT quota from the Reserve category to the General category for the remainder of 2012 and adjusted the daily retention limit for the 2013 January subquota period from the default level of one large medium or giant BFT to two large medium or giant BFT (77 FR 74612, December 17, 2012). That retention limit was effective from January 1, 2013, until February 15, 2013, when NMFS closed the fishery because the January subquota had been met (78 FR 11788, February 20, 2013).

Adjustment of General Category Daily Retention Limit

Under § 635.23(a)(4), NMFS may increase or decrease the daily retention limit of large medium and giant BFT over a range of zero to a maximum of five per vessel based on consideration of the relevant criteria provided under § 635.27(a)(8), which include: The usefulness of information obtained from catches in the particular category for biological sampling and monitoring of the status of the stock; effects of the adjustment on BFT rebuilding and overfishing; effects of the adjustment on accomplishing the objectives of the fishery management plan; variations in seasonal BFT distribution, abundance, or migration patterns; effects of catch rates in one area precluding vessels in another area from having a reasonable

opportunity to harvest a portion of the category's quota; and review of dealer reports, daily landing trends, and the availability of BFT on the fishing grounds.

NMFS has considered these criteria and their applicability to the General category BFT retention limit for the June–August 2013 General category fishery. These considerations include, but are not limited to, the following. Biological samples collected from BFT landed by General category fishermen and provided by BFT dealers continue to provide NMFS with valuable parts and data for ongoing scientific studies of BFT age and growth, migration, and reproductive status. As this action would be taken consistent with the quotas previously established and analyzed in the 2011 BFT quota final rule (76 FR 39019, July 5, 2011), and consistent with objectives of the 2006 Consolidated HMS FMP, it is not expected to negatively impact stock health. A principal consideration is the objective of providing opportunities to harvest the full June–August subquota without exceeding it based upon the 2006 Consolidated HMS FMP goal: ''Consistent with other objectives of this FMP, to manage Atlantic HMS fisheries for continuing optimum yield so as to provide the greatest overall benefit to the Nation, particularly with respect to food production, providing recreational opportunities, preserving traditional fisheries, and taking into account the protection of marine ecosystems.'' Migration of commercial-size BFT to the fishing grounds off the northeast U.S. coast is anticipated by early June. Lastly, based on General category landings rates during the June through August time period over the last several years, it is highly unlikely that the June through August subquota will be filled with the default daily retention limit of one BFT per vessel. During the June–August 2012 period, under a three-fish limit, BFT landings were approximately 155 mt (71 percent of the percent of the available quota for that period).

A lower limit could result in unused quota being added to the later portion of the General category season (i.e., rolling forward to the subsequent subquota time period). Increasing the daily retention limit from the default may mitigate rolling an excessive amount of unused quota from one time-period subquota to the next. Increasing the daily limit from three to four or five fish may risk exceeding the available June–August subquota.

Based on these considerations, NMFS has determined that a three-fish General category retention limit is warranted. It would provide a reasonable opportunity to harvest the U.S. quota of BFT, without exceeding it, while maintaining an equitable distribution of fishing opportunities; help achieve optimum yield in the General category BFT fishery; allow the collection of a broad range of data for stock monitoring purposes; and be consistent with the objectives of the 2006 Consolidated HMS FMP. Therefore, NMFS increases the General category retention limit from the default limit to three large medium or giant BFT per vessel per day/trip, effective June 1, 2013, through August 31, 2013.

Regardless of the duration of a fishing trip, the daily retention limit applies upon landing. For example, whether a vessel fishing under the General category limit takes a two-day trip or makes two trips in one day, the daily limit of three fish may not be exceeded upon landing. This General category retention limit is effective in all areas, except for the Gulf of Mexico, and applies to those vessels permitted in the General category, as well as to those HMS Charter/Headboat permitted vessels fishing commercially for BFT.

Monitoring and Reporting

NMFS will continue to monitor the BFT fishery closely through the mandatory dealer landing reports, which NMFS requires to be submitted within 24 hours of a dealer receiving BFT. Depending on the level of fishing effort and catch rates of BFT, NMFS may determine that additional retention limit adjustment or closure is necessary to ensure available quota is not exceeded or to enhance scientific data collection from, and fishing opportunities in, all geographic areas.

Closures or subsequent adjustments to the daily retention limits, if any, will be published in the **Federal Register**. In addition, fishermen may call the Atlantic Tunas Information Line at (888) 872–8862 or (978) 281–9260, or access *www.hmspermits.noaa.gov*, for updates on quota monitoring and retention limit adjustments.

Classification

The Assistant Administrator for NMFS (AA) finds that it is impracticable and contrary to the public interest to provide prior notice of, and an opportunity for public comment on, this action for the following reasons:

The regulations implementing the 2006 Consolidated HMS FMP provide for inseason retention limit adjustments to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. Affording prior notice and opportunity for public comment to implement these retention limits is impracticable as NMFS needs to wait until it has necessary data and information about the fishery before it can select the appropriate retention limit for a time period prescribed by regulation. By the time NMFS has the necessary data, implementing the retention limit following a public comment period would preclude fishermen from harvesting BFT that are legally available consistent with all of the regulatory criteria. Analysis of available data shows that the General category BFT retention limits may be increased with minimal risks of exceeding the ICCAT-allocated quota.

Delays in increasing these retention limits would adversely affect those General and Charter/Headboat category vessels that would otherwise have an opportunity to harvest more than the default retention limit of one BFT per day/trip and may exacerbate the problem of low catch rates and quota rollovers. Limited opportunities to harvest the respective quotas may have negative social and economic impacts for U.S. fishermen that depend upon catching the available quota within the time periods designated in the 2006 Consolidated HMS FMP. Adjustment of the retention limit needs to be effective June 1, 2013, or as soon as possible thereafter, to minimize any unnecessary disruption in fishing patterns, to allow the impacted sectors to benefit from the adjustment, and to not preclude fishing opportunities for fishermen who have access to the fishery only during this time period. Therefore, the AA finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment. For these reasons, there is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

This action is being taken under 50 CFR 635.23(a)(4) and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: May 3, 2013.

James P. Burgess,

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

[FR Doc. 2013–10931 Filed 5–7–13; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 78, No. 89
Wednesday, May 8, 2013

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket No. EERE–2011–BT–TP–0061]

RIN 1904–AC65

Energy Conservation Program for Consumer Products and Certain Commercial and Industrial Equipment: Test Procedures for Showerheads, Faucets, Water Closets, Urinals and Commercial Prerinse Spray Valves

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

ACTION: Notice of extension of public comment period.

SUMMARY: On April 8, 2013, the U.S. Department of Energy (DOE) published a supplemental notice of proposed rulemaking (SNOPR) for test procedures for showerheads, faucets, water closets, urinals and commercial prerinse spray valves in the **Federal Register**. This document announces an extension of the public comment period for submitting comments on the SNOPR or any other aspect of this test procedure rulemaking. The comment period is extended to June 7, 2013.

DATES: DOE will accept comments, data, and information regarding this rulemaking received no later than June 7, 2013.

ADDRESSES: Any comments submitted must identify the SNOPR for test procedures for showerheads, faucets, water closets, urinals and commercial prerinse spray valves and provide docket number EERE–2011–BT–TP–0061 and/or Regulation Identification Number (RIN) 1904–AC65, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: PlumbingPrds-2011–TP–0061@ee.doe.gov.* Include the docket number EERE–2011–BT–TP–0061 and/or RIN 1904–AC65 in the subject line of the message.
- *Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies. [Please note that comments and CDs sent by mail are often delayed and may be damaged by mail screening processes.]
- *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 950 L'Enfant Plaza, SW., Suite 600, Washington, DC 20024. Telephone (202) 586–2945. If possible, please submit all items on CD, in which case it is not necessary to include printed copies.

Docket: The docket is available for review at *www.regulations.gov,* including **Federal Register** notices, framework documents, public meeting attendee lists and transcripts, comments, and other supporting documents/materials. All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The rulemaking Web page can be found at:

http://www1.eere.energy.gov/buildings/appliance_standards/rulemaking.aspx/ruleid/15.

This Web page contains links to the interim technical support document and other supporting materials and information for this rulemaking on the *regulations.gov* site. The regulations.gov Web page contains instructions on how to access all documents in the docket, including public comments.

FOR FURTHER INFORMATION CONTACT: Mr. Lucas Adin, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies, EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 287–1317. Email: *Lucas.Adin@ee.doe.gov.*

In the Office of the General Counsel, contact Ms. Jennifer Tiedeman, U.S. Department of Energy, Office of the General Counsel, GC–71, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–6111. Email: *Jennifer.Tiedeman@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: On April 8, 2013, DOE published a supplemental notice of proposed rulemaking (SNOPR) in the **Federal Register** (78 FR 20832) to propose amendments to its May 2012 notice of proposed rulemaking related to test procedures for showerheads, faucets, water closets, urinals, and commercial prerinse spray valves. The notice provided for the submission of comments by May 8, 2013. Plumbing Manufacturers International (PMI) has requested a 30-day extension of the comment period, stating that it needs additional time to fully evaluate the amendments proposed in the SNOPR with all of its members. DOE has determined that an extension of the public comment period is appropriate based on the foregoing reason and is hereby extending the comment period. DOE will consider any comments received by midnight on June 7, 2013, and deems any comments received by that time to be timely submitted.

Issued in Washington, DC, on May 1, 2013.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2013–10915 Filed 5–7–13; 8:45 am]

BILLING CODE 6450–01–P

FARM CREDIT ADMINISTRATION

12 CFR Part 652

RIN 3052–AC83

Federal Agricultural Mortgage Corporation Funding and Fiscal Affairs; Farmer Mac Liquidity Management

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Farm Credit Administration (FCA) Board reopens the comment period for 30 days on the proposed rule that would amend its liquidity management regulations for the Federal Agricultural Mortgage Corporation (Farmer Mac). Reopening the comment period will afford interested parties a new opportunity to comment on the proposed liquidity regulations.

DATES: Please send your comments to us on or before June 7, 2013.

ADDRESSES: We offer a variety of methods for you to submit comments on this proposed rule. For accuracy and efficiency reasons, commenters are encouraged to submit comments by email or through the Agency's Web site. As facsimiles (fax) are difficult for us to process and achieve compliance with section 508 of the Rehabilitation Act, we are no longer accepting comments submitted by fax. Regardless of the method you use, please do not submit your comment multiple times via different methods. You may submit comments by any of the following methods:

- *Email:* Send us an email at *reg-comm@fca.gov.*
- *FCA Web site: http://www.fca.gov.* Select ''Public Commenters,'' then ''Public Comments,'' and follow the directions for ''Submitting a Comment.''
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Laurie A. Rea, Director, Office of Secondary Market Oversight, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102–5090.

You may review copies of all comments we receive at our office in McLean, Virginia, or on our Web site at *http://www.fca.gov.* Once you are in the Web site, select ''Public Commenters,'' then ''Public Comments,'' and follow the directions for ''Reading Submitted Public Comments.'' We will show your comments as submitted, but for technical reasons we may omit items such as logos and special characters. Identifying information that you provide, such as phone numbers and addresses, will be publicly available. However, we will attempt to remove email addresses to help reduce Internet spam.

FOR FURTHER INFORMATION CONTACT:

Joseph T. Connor, Associate Director for Policy and Analysis, Office of Secondary Market Oversight, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4280, TTY (703) 883–4434;

Or

Richard Katz, Senior Counsel, Office of the General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TTY (703) 883–4020.

SUPPLEMENTARY INFORMATION: On November 18, 2011, we published a notice of proposed rulemaking to revise Farmer Mac's non-program investment and liquidity requirements.[1] The 60-day comment period ended on January 17, 2012. The proposed rulemaking covered several topics. The FCA decided to finalize several of the proposed regulations separately in different phases of this rulemaking.[2] This phase of the rulemaking focuses on Farmer Mac's liquidity by addressing four definitions in § 652.5,[3] liquidity management in § 652.35, and the liquidity reserve and the supplemental liquidity buffer in § 652.40.

We received a letter dated April 17, 2013 from Farmer Mac that asked us to reopen the comment period for 30 days on proposed § 652.40. Farmer Mac informed us that after the final investment management rule became effective, it ''commenced an evaluation and rebalancing of its investment portfolio in the context of the proposed liquidity requirements'' set forth in proposed § 652.40. Farmer Mac believes that this evaluation process exposed possible concerns regarding the liquidity requirements in the proposed regulation, which in its opinion, may merit further consideration by the FCA before a final rule is enacted.

In response to this request, we are reopening the comment period for all of the above-referenced liquidity regulations for an additional 30 days. Based on the circumstances that Farmer Mac identified in its April 17, 2013 letter, reopening the comment period ensures the transparency and fairness of the rulemaking process in accordance with the requirements of the Administrative Procedure Act. In addition, because the proposed rule would increase Farmer Mac's minimum liquidity reserve requirement from 60 days to 90 days, FCA believes it is important to receive thorough comment on the impact of the proposal. The FCA invites all interested parties to provide additional comments about proposed §§ 652.35 and 652.40, and the four liquidity-related definitions in proposed § 652.5.

Dated: May 1, 2013.

Dale L. Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2013–10821 Filed 5–7–13; 8:45 am]

BILLING CODE 6705–01–P

[1] 76 FR 71798 (Nov. 18, 2011).

[2] On November 5, 2012, the FCA enacted final regulations governing investment management at Farmer Mac. This final rule amended §§ 652.10, 652.15, 652.25, 652.30, and 652.45. *See* 77 FR 66375. In a later phase of this rulemaking, we plan to enact a final rule pertaining to eligible investments that Farmer Mac may purchase and hold.

[3] The four definitions pertaining to liquidity are ''Cash,'' ''Contingency Funding Plan,'' ''Liquidity Maturity Management Plan,'' and ''Liquidity reserve.''

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0399; Directorate Identifier 2011–SW–064–AD]

RIN 2120–AA64

Airworthiness Directives; Eurocopter France Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Eurocopter France (Eurocopter) Model EC 155B, EC155B1, SA–365N, SA–365N1, AS–365N2, AS 365 N3, and SA–366G1 helicopters. This proposed AD would require inspecting the collective pitch lever for correct locking and unlocking conditions. This proposed AD is prompted by two separate reports of inadvertent collective pitch lever locking and unlocking. The proposed actions are intended to detect an incorrectly adjusted collective pitch lever, which could result in loss of control of the helicopter.

DATES: We must receive comments on this proposed AD by July 8, 2013.

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

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed AD, contact American Eurocopter Corporation, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *http://www.eurocopter.com/techpub.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

FOR FURTHER INFORMATION CONTACT: Matt Wilbanks, Aviation Safety Engineer, Rotorcraft Certification Office, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5110; email *matt.wilbanks@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD No. 2011–0154, dated August 22, 2011, to correct an unsafe condition for Eurocopter Model EC 155B, EC155B1, SA–365N, SA–365N1, AS–365N2, AS 365 N3, and SA–366G1 helicopters. EASA advises that two occurrences have been reported of inadvertent locking and unlocking of the collective pitch lever. One inadvertent collective pitch lever locking occurred when moving the collective pitch lever to the low-pitch position, and one inadvertent collective pitch lever unlocking occurred during engine start. To address this unsafe condition, Eurocopter issued AS 365 Alert Telex No. 67.00.10, SA 366 Alert Telex No. 67.05, and EC 155 Alert Telex No. 67A007, which describe procedures to inspect the collective pitch lever for correct locking and unlocking conditions. This inspection was mandated by Direction Générale de l'Aviation Civile (DGAC) France AD No. F–2005–127, dated July 20, 2005. DGAC subsequently revised its AD, No. F–2005–127 R1, dated February 1, 2006 (DGAC AD F–2005–127 R1), after Eurocopter issued Alert Service Bulletins containing the same inspection procedures and bearing the same numbers as the Alert Telexes. Since the issuance of DGAC AD F–2005–127 R1 Eurocopter developed an assembly comprised of a blade, a hinge, and a return spring to replace the flexible collective lever locking blade as terminating action for the inspection required by the AD. EASA then issued AD No. 2011–0154, dated August 22, 2011 (EASA AD 2011–0154), which superseded DGAC AD F–2005–127 R1, retaining the inspection procedures for the collective pitch lever and removing from the applicability helicopters with the hinged, spring-loaded collective lever locking blade installed, designated as modification (MOD) 0767B65.

FAA's Determination

These helicopters have been approved by the aviation authority of France and are approved for operation in the United States. Pursuant to our bilateral agreement with France, EASA, its technical representative, has notified us of the unsafe condition described in its AD. We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition is likely to exist or develop on other products of the same type design.

Related Service Information

We reviewed Eurocopter Alert Service Bulletin (ASB) No. 67.00.10 for Model AS365 helicopters, ASB No. 67.05 for Model SA366 helicopters, and ASB No. 67A007 for Model EC155 helicopters. All three ASBs are Revision 1 and are dated February 25, 2009. These ASBs describe procedures for inspecting and adjusting the collective pitch lever for correct locking and unlocking conditions.

Eurocopter has also issued ASB No. 67.00.12, Revision 0, dated February 25, 2009, for Model AS365 helicopters; ASB No. 67.07, Revision 0, dated February 25, 2009, for Model AS366 helicopters; and ASB No. 67–009, Revision 1, dated July 19, 2010, for Model EC 155 helicopters. These ASBs contain the procedures for MOD 0767B65.

Proposed AD Requirements

This proposed AD would require:

- Inspecting the collective pitch lever for correct unlocking with a spring scale.
- If the collective pitch lever unlocks outside of the correct ''G'' load, adjusting the collective pitch lever restraining tab and, for certain models, adjusting the collective link rods.
- Inspecting the collective pitch lever for the risk of inadvertent locking by measuring the clearance between the locking pin of the collective pitch lever and the L-section of the restraining tab.
- If the clearance between the locking pin of the collective pitch lever and the L-section of the restraining tab is incorrect, modifying the tab with a slight bend to the tab.

Costs of Compliance

We estimate that this proposed AD would affect 32 helicopters of U.S. Registry.

We estimate that operators may incur the following costs in order to comply with this AD. Inspecting and adjusting the collective pitch lever would require about 1 work hour at an average labor rate of $85 per hour, for a total cost per helicopter of $85 and a cost to U.S. operators of $2,720.

Authority for This Rulemaking

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

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

Regulatory Findings

We determined that this proposed AD would not have federalism implications

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

For the reasons discussed, I certify this proposed regulation:

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Eurocopter France: Docket No. FAA–2013–0399; Directorate Identifier 2011–SW–064–AD.

(a) Applicability

This AD applies to Model EC 155B, EC155B1, SA–365N, SA–365N1, AS–365N2, AS 365 N3, and SA–366G1 helicopters, except helicopters with modification (MOD) 0767B5 installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as inadvertent locking and unlocking of the collective pitch lever, which could result in subsequent loss of control of the helicopter.

(c) Reserved

(d) Compliance

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

(e) Required Actions

Within 50 hours time-in-service:

(1) For Model EC155B and EC155B1 helicopters:

(i) Lock the collective pitch lever, and using a spring scale, measure the load (G) required to unlock the pilot's collective pitch lever as depicted in Figure 1, Detail B of Eurocopter Alert Service Bulletin (ASB) No. 67A007, Revision 1, dated February 25, 2009 (ASB 67A007).

(ii) If the collective pitch lever unlocks at a load less than 11 deca Newtons (daN) (24.7 lbs) or greater than 14 daN (31.5 lbs), before further flight, adjust the collective pitch lever restraining tab (F) using the oblong holes.

(iii) Set the collective pitch lever to the ''low pitch'' position and hold it in this position, without forcing it downwards.

(iv) Measure the clearance (J1) between the locking pin of the collective pitch lever (C) and the L-section of the restraining tab (F) as depicted in Figure 1, Detail A of ASB 67A007.

(v) If the clearance between the locking pin of the collective pitch lever and the L-section of the restraining tab is less than 3 millimeters (mm), before further flight, remove the restraining tab, clamp the restraining tab (F) in a vice with soft jaws, and gradually apply a load (H) to ensure a clearance of 3 mm or more, as depicted in Figure 1, Detail K of ASB 67A007.

(2) For Model SA–365N, SA–365N1, AS–365N2, and AS 365 N3 helicopters:

(i) Completely loosen the friction, lock the collective pitch lever, and using a spring scale, measure the load (G) required to unlock the pilot's collective pitch lever as depicted in Figure 1, Detail B of Eurocopter ASB No. 67.00.10, Revision 1, dated February 25, 2009 (ASB 67.00.10).

(ii) If the collective pitch lever unlocks at a load less than 5 daN (11.3 lbs) or greater than 14 daN (31.5 lbs), before further flight, adjust the collective pitch lever restraining tab (F) using the oblong holes and adjust the collective link rods as described in the Accomplishment Instructions, paragraph 2.B.4., of ASB 67.00.10.

(iii) Set the collective pitch lever to the ''low pitch'' position and hold it in this position, without forcing it downwards.

(iv) Tighten the friction lock and measure the clearance (J1) between the locking pin of the collective pitch lever (C) and the L-section of the restraining tab (F) as depicted in Figure 1, Detail A of ASB 67.00.10.

(v) If the clearance between the locking pin of the collective pitch lever and the L-section of the restraining tab is less than 3 mm, before further flight, remove the restraining tab, clamp the restraining tab (F) in a vice with soft jaws, and gradually apply a load (H) to ensure a clearance of 3 mm or more, as depicted in Figure 1, Detail K, of ASB 67.00.10.

(3) For Model SA–366G1 helicopters:

(i) Completely loosen the friction, lock the collective pitch lever, and using a spring scale, measure the load (G) required to unlock the pilot's collective pitch lever as depicted in Figure 1, Detail B of Eurocopter ASB No. 67.05, Revision 1, dated February 25, 2009 (ASB 67.05).

(ii) If the collective pitch lever unlocks at a load less than 5 daN (11.3 lbs) or greater than 14 daN (31.5 lbs), before further flight, adjust the collective pitch lever restraining tab (F) using the oblong holes and adjust the collective link rods as described in the Accomplishment Instructions, paragraph 2.B.4., of ASB 67.05.

(iii) Set the collective pitch lever to the ''low pitch'' position and hold it in this position, without forcing it downwards.

(iv) Tighten the friction lock and measure the clearance (J1) between the locking pin of the collective pitch lever (C) and the L-section of the restraining tab (F) as depicted in Figure 1, Detail A, of ASB 67.05.

(v) If the clearance between the locking pin of the collective pitch lever and the L-section of the restraining tab is less than 3 mm, before further flight, remove the restraining tab, clamp the restraining tab (F) in a vice with soft jaws, and gradually apply a load (H) to ensure a clearance of 3 mm or more, as depicted in Figure 1, Detail K, of ASB 67.05.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Matt Wilbanks, Aviation Safety Engineer, Rotorcraft Certification Office, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5110; email matt.wilbanks@faa.gov.

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

(g) Additional Information

(1) The subject of this AD is addressed in European Aviation Safety Agency AD No. 2011–0154, dated August 22, 2011.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 6710: Main Rotor Control.

Issued in Fort Worth, Texas, on April 26, 2013.

Kim Smith,

Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2013–10909 Filed 5–7–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0398; Directorate Identifier 2011–SW–065–AD]

RIN 2120–AA64

Airworthiness Directives; Eurocopter Deutschland GmbH Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Eurocopter Deutschland GmbH (ECD) Model EC135P1, EC135P2, EC135P2+, EC135T1, EC135T2, and EC135T2+ helicopters with certain fire extinguishing systems installed. This proposed AD would require modifying the fire extinguishing system injection tubes. This proposed AD is prompted by a report that the injection tubes are deforming due to heat. The proposed actions are intended to prevent deformation of the fire extinguishing system injection tubes during a fire, which could result in impaired distribution of the fire extinguishing agent, failure of the fire extinguishing system to contain an engine fire, and subsequent loss of control of the helicopter.

DATES: We must receive comments on this proposed AD by July 8, 2013.

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

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed AD, contact American Eurocopter Corporation, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *http://www.eurocopter.com/techpub.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

FOR FURTHER INFORMATION CONTACT: Matt Wilbanks, Aviation Safety Engineer, Rotorcraft Certification Office, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5110; email *matt.wilbanks@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD No. 2011–0172, dated September 7, 2011 (AD 2011–0172), to correct an unsafe condition for ECD Model EC 135 P1, EC 135 P2, EC 135 P2+, EC 135 T1, EC 135 T2, EC 135 T2+, EC 635 T1, EC 635 P2+, and EC 635 T2+ helicopters with a single engine fire extinguishing system, part number (P/N) L262M1808101, P/N L262M1812101, or P/N L262M1812102, or with a dual engine fire extinguishing system, P/N L262M1813102, installed. EASA advises that the fire extinguishing system injection tubes on Model EC 135 and EC 635 helicopters ''are not compliant with the relevant airworthiness requirements, because they are also forming part of the firewall.'' According to EASA, during an engine fire, this condition may affect the function of the fire extinguishing system and degrade the fire containment capability of the system to the extent that it is incapable of extinguishing an engine fire. For these reasons, EASA issued AD 2011–0172, which requires modification of the affected injection tubes by removing part of the tubing and replacing it with a section of heat-resistant injection tubing.

FAA's Determination

These helicopters have been approved by the aviation authority of the Federal Republic of Germany and are approved for operation in the United States. Pursuant to our bilateral agreement with the Federal Republic of Germany, EASA, its technical representative, has notified us of the unsafe condition described in its AD. We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition is likely to exist or develop on other products of the same type design.

Related Service Information

ECD has issued EC135 Alert Service Bulletin (ASB) No. EC135–26A–003, Revision 2, dated December 19, 2011, which describes procedures to remove a section of the fire extinguishing system injection tubing and replace it with heat-resistant injection tubing.

Proposed AD Requirements

This proposed AD would require, within 30 days, cutting out a portion of the existing injection tubes and replacing that portion with a section of new injection tubing.

Differences Between This Proposed AD and the EASA AD

The EASA AD applies to helicopters with a dual engine fire extinguishing system and this proposed AD does not because these systems are only installed on helicopters operated by the German Federal Police and are not operated in the U. S. Also, the EASA AD applies to Model EC635 helicopters, and the proposed AD does not because the

EC635 is not type-certificated in the U.S.

Costs of Compliance

We estimate that this proposed AD would affect 246 helicopters of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this AD. Modifying the injection tubes would require about 4.5 work-hours at an average labor rate of $85 per hour and required parts would cost about $900, for a cost of $1,282 per helicopter and a total cost to U.S. operators of $315,372.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;
2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Eurocopter Deutschland GmbH: Docket No. FAA–2013–0398; Directorate Identifier 2011–SW–065–AD.

(a) Applicability

This AD applies to Eurocopter Deutschland GmbH (ECD) Model EC135P1, EC135P2, EC135P2+, EC135T1, EC135T2, and EC135T2+ helicopters with a fire extinguishing system part number (P/N) L262M1808101, P/N L262M1812101, or P/N L262M1812102 installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as deformation of the fire extinguishing system injection tubes during an engine fire, which could result in impaired distribution of the fire extinguishing agent, failure of the fire extinguishing system to contain a fire, and subsequent loss of control of the helicopter.

(c) Comments Due Date

We must receive comments by July 8, 2013.

(d) Compliance

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

(e) Required Actions

(1) Within 30 days, modify each fire extinguishing system injection tube by removing and replacing a section of the tubing in accordance with the Accomplishment Instructions, paragraph 3.B., of Eurocopter EC135 Alert Service Bulletin No. EC135–26A–003, Revision 2, dated December 19, 2011.

(2) Do not install an injection tube, P/N L262M1810101, P/N L262M1811801, or P/N L262M1809101, on any helicopter unless it has been modified as required by this AD.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Matt Wilbanks, Aviation Safety Engineer, Rotorcraft Certification Office, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5110; email *matt.wilbanks@faa.gov.*

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

(g) Additional Information

(1) The subject of this AD is addressed in European Aviation Safety Agency AD No. 2011–0172, dated September 7, 2011.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 2620: Extinguishing System.

Issued in Fort Worth, Texas, on April 26, 2013.

Kim Smith,

Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2013–10911 Filed 5–7–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0365; Directorate Identifier 2012–NM–223–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede an existing airworthiness directive (AD) that applies to all Airbus Model A330–200 and –300 series airplanes, and Model A340–200 and –300 series airplanes. The existing AD currently requires a repetitive inspection program on certain check valves in the hydraulic systems that includes, among other things, inspections for lock wire presence and integrity, traces of seepage or black deposits, proper torque, alignment of the check valve and manifold, installing new lock wire, and corrective actions if needed. Since we issued that AD, additional in-service reports of check valves loosening at lower flight cycle thresholds than previously reported have been received. This proposed AD would expand the applicability, reduce the compliance

time, change torque values of the check valve tightening, and require a repetitive inspection program for certain check valves in the hydraulic systems on airplanes that have had a certain modification embodied during production or in-service. We are proposing this AD to detect and correct such check valve loosening, which could result in hydraulic leaks, possibly leading to the loss of all three hydraulic systems and consequent loss of control of the airplane.

DATES: We must receive comments on this proposed AD by June 24, 2013.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, 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.

For service information identified in this proposed AD, contact Airbus SAS—Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *airworthiness.A330-A340@airbus.com;* Internet *http://www.airbus.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1138; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–0365; Directorate Identifier 2012–NM–223–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

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

Discussion

On November 16, 2009, we issued AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009). That AD required actions intended to address an unsafe condition on Airbus Model A330–200 and –300 series airplanes, and Model A340–200 and –300 series airplanes.

Since we issued AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009), the European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2012–0244R1, dated January 25, 2013 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> An A330 operator experienced a yellow hydraulic circuit low level due to a loose check valve, Part Number (P/N) CAR401. During the inspection on the other two hydraulic systems, the other three check valves P/N CAR401 were also found to be loose with their lock wire broken in two instances. Airbus A340 aeroplanes are also equipped with P/N CAR401 high pressure manifold check valves.
>
> Additional cases of P/N CAR401 check valve loosening have been reported on aeroplanes having accumulated more than 1,000 [total] flight cycles (FC). The check valve fitted on the Yellow hydraulic system is more affected, due to additional system cycles induced by cargo door operation.
>
> This condition, if not detected and corrected, could result in hydraulic leaks, possibly leading to the loss of all three hydraulic systems and consequent loss of control of the aeroplane.
>
> To address this unsafe condition, EASA issued Emergency AD 2009–0223–E [which corresponds to FAA AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009)] to require an inspection programme to detect any check valve loosening and if necessary, to apply the applicable corrective actions.
>
> EASA AD 2010–0145, which superseded EASA EAD 2009–0223–E retaining its requirements, was issued to expand the applicability to the newly certified models A330–223F and A330–243F.
>
> Prompted by further reported in-service events of check valve P/N CAR401 loosening before reaching the threshold of 700 FC, EASA AD 2011–0139, which superseded EASA AD 2010–0145, retaining its requirements, was issued to:
>
> —extend the requirement to identify the P/N CAR401 check valves to all aeroplanes, and to
>
> —reduce the inspection threshold for aeroplanes fitted with check valve P/N CAR401, either installed in production through Airbus modification 54491, or installed in service through Airbus Service Bulletin (SB) A330–29–3101 or Airbus SB A340–29–4078.
>
> EASA AD 2012–0070, which superseded EASA AD 2011–0139, retaining its requirements, was issued to require an increased torque value of the check valve tightening and High Pressure (HP) manifold re-identification.
>
> Since EASA AD 2012–0070 was issued, additional in-service events have been reported on aeroplanes fitted with check valves on which the increased torque value had been applied. Based on those events, it has been concluded that the action to re-torque the check valves with an increased value is not a satisfactory terminating action for addressing the issue of those check valves.
>
> For the reasons described above, this new [EASA] AD partially retains the requirements of EASA AD 2012–0070, which is superseded. Additionally, for aeroplanes equipped with P/N CAR401 on which the increased torque value has been applied, this new [EASA] AD requires repetitive inspections of the check valves and HP manifolds. Finally, this [EASA] AD also requires application of a lower torque value when a check valve P/N CAR401 is installed on an aeroplane.
>
> This [EASA] AD is considered to be an interim action and further AD action may follow.
>
> Note: the reporting and the torque value increase requirements for check valves P/N CAR401 of EASA AD 2012–0070 are no longer part of this new [EASA] AD.

This proposed AD would expand the applicability to include Model A330–200 freighter series airplanes, reduce the compliance time for initial inspection, and change torque values of the check valve tightening. The corrective actions include replacing seal assemblies, re-torquing the check valve, and replacing the lock wire.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Airbus has issued the following service information.

- Airbus Alert Operators Transmission A29L001–12, dated October 11, 2012.
- Airbus Mandatory Service Bulletin A330–29–3111, Revision 02, dated June 23, 2011.
- Airbus Mandatory Service Bulletin A340–29–4086, Revision 02, dated June 23, 2011.

The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 67 products of U.S. registry.

The actions that are required by AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009), and retained in this proposed AD take about 8 work-hours per product, at an average labor rate of $85 per work hour. Based on these figures, the estimated cost of the currently required actions is $680 per product.

We estimate that it would take about 2 work-hours per product to comply with the new basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $11,390, or $170 per product.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this proposed AD.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

1. Is not a ''significant regulatory action'' under Executive Order 12866;
2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009), and adding the following new AD:

Airbus: Docket No. FAA–2013–0365; Directorate Identifier 2012–NM–223–AD.

(a) Comments Due Date

We must receive comments by June 24, 2013.

(b) Affected ADs

This AD supersedes AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009).

(c) Applicability

This AD applies to Airbus Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes; and Model A340–211, –212, –213, –311, –312, and –313 airplanes; certificated in any category; all manufacturer serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 29, Hydraulic Power.

(e) Reason

This AD was prompted by multiple reports of hydraulic line check valves loosening. We are issuing this AD to detect and correct such check valve loosening, which could result in hydraulic leaks, possibly leading to the loss of all three hydraulic systems and consequent loss of control of the airplane.

(f) Compliance

You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

(g) Retained Actions

This paragraph restates the requirements of paragraph (g) of AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009). Except for Model A330–223F and A330–243F airplanes: Do the actions required by paragraphs (g)(1) and (g)(2) of this AD.

(1) For airplanes that do not have Airbus Modification 54491 embodied in production, or Airbus Service Bulletin A330–29–3101 or Airbus Service Bulletin A340–29–4078 embodied in service: Within 100 flight cycles or 28 days after December 14, 2009 (the effective date of AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009)), whichever occurs first, inspect the check valves on the blue, green, and yellow hydraulic systems to identify their part numbers (P/Ns), in accordance with the instructions of Airbus All Operators Telex (AOT) A330–29A3111, Revision 1, dated October 8, 2009 (for Model A330–200 and -300 series airplanes); or AOT A340–29A4086, Revision 1, dated October 8, 2009 (for Model A340–200 and –300 series airplanes). Accomplishment of the inspection required by paragraph (h) of this AD terminates the requirements of this paragraph.

(i) If check valves having P/N CAR401 are installed on all three hydraulic systems, before further flight, do the actions specified in paragraph (g)(2)(i) of this AD. After accomplishing the actions required by paragraph (g)(2)(i) of this AD, do the actions specified in paragraphs (g)(2)(ii) and

(g)(2)(iii) of this AD at the applicable compliance times specified in those paragraphs. Accomplishment of the inspection required by paragraph (i) of this AD terminates the requirements of this paragraph.

(ii) If check valves having P/N CAR401 are not installed on all three hydraulic systems, no further action is required by this paragraph until any check valve having P/N CAR400 is replaced with a check valve having P/N CAR401. If any check valve having P/N CAR400 is replaced by a check valve having P/N CAR401, before further flight, do the inspection specified in paragraph (g)(1) of this AD to determine if all three hydraulic systems are equipped with check valves having P/N CAR401. Accomplishment of the inspection required by paragraph (h) of this AD terminates the requirements of this paragraph.

(2) For airplanes on which Airbus Modification 54491 was embodied in production, or Airbus Service Bulletin A330–29–3101 or Airbus Service Bulletin A340–29–4078 was embodied in service, do the actions specified in paragraphs (g)(2)(i), (g)(2)(ii), and (g)(2)(iii) of this AD.

(i) Except as required by paragraph (g)(1)(i) of this AD, at the applicable times specified in paragraphs (g)(2)(i)(A) and (g)(2)(i)(B) of this AD, as applicable: Do the inspection program (detailed inspection of the lock wire for presence and integrity, a detailed inspection for traces of seepage or black deposits, and an inspection for proper torque) on yellow and blue high pressure manifolds, install new lock wires, and do all applicable corrective actions, in accordance with the instructions of paragraph 4.1.1 of Airbus AOT A330–29A3111, Revision 1, dated October 8, 2009 (for Model A330–200 and –300 series airplanes); or AOT A340–29A4086, Revision 1, dated October 8, 2009 (for Model A340–200 and –300 series airplanes). Do all applicable corrective actions before further flight. Accomplishment of the inspection required by paragraph (h)(1) of this AD terminates the requirements of this paragraph.

(A) For airplanes on which Airbus Modification 54491 has been embodied in production: At the later of the times specified in paragraphs (g)(2)(i)(A)(*1*) and (g)(2)(i)(A)(*2*) of this AD.

(*1*) Before the accumulation of 1,000 total flight cycles since first flight but no earlier than the accumulation of 700 total flight cycles since first flight.

(*2*) Within 100 flight cycles or 28 days after December 14, 2009 (the effective date of AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009)), whichever occurs first.

(B) For airplanes on which Airbus Service Bulletin A330–29–3101 or A340–29–4078 was embodied in service: At the later of the times specified in paragraphs (g)(2)(i)(B)(*1*) and (g)(2)(i)(B)(*2*) of this AD.

(*1*) Within 1,000 flight cycles since the embodiment of Airbus Service Bulletin A330–29–3101 or A340–29–4078 but no earlier than 700 flight cycles after the embodiment of Airbus Service Bulletin A330–29–3101 or A340–29–4078.

(*2*) Within 100 flight cycles or 28 days after December 14, 2009 (the effective date of AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009)), whichever occurs first.

(ii) Within 900 flight hours after accomplishment of paragraph (g)(2)(i) of this AD, do the inspection program (detailed inspection of the lock wire for presence and integrity, a detailed inspection for traces of seepage or black deposits, and an inspection for proper torque) and install a new lock wire on the green high pressure manifold; and do an inspection (detailed inspection for traces of seepage or black deposits, and detailed inspection to determine alignment of the check valve and manifold) on the yellow and blue high pressure manifolds, and do all applicable corrective actions; in accordance with the instructions of paragraph 4.1.2 of Airbus AOT A330–29A3111, Revision 1, dated October 8, 2009 (for Model A330–200 and –300 series airplanes); or AOT A340–29A4086, Revision 1, dated October 8, 2009 (for Model A340–200 and –300 series airplanes). Do all applicable corrective actions before further flight. Accomplishment of the inspection program required by paragraph (i) of this AD terminates the requirements of this paragraph.

(iii) Within 900 flight hours after accomplishment of paragraph (g)(2)(ii) of this AD, and thereafter at intervals not to exceed 900 flight hours, do the inspection program (detailed inspection for traces of seepage or black deposits, and detailed inspection to determine alignment of the check valve and manifold) on the green, yellow, and blue high pressure manifolds, and do all applicable corrective actions, in accordance with the instructions of paragraph 4.1.3 of Airbus AOT A330–29A3111, Revision 1, dated October 8, 2009 (for Model A330–200 and –300 series airplanes); or AOT A340–29A4086, Revision 1, dated October 8, 2009 (for Model A340–200 and –300 series airplanes). Do all applicable corrective actions before further flight. Accomplishment of the inspection program required by paragraph (i) of this AD terminates the requirements of this paragraph.

(h) New Inspection and Actions

For airplanes equipped with check valves having P/N CAR400; and for airplanes equipped with check valves having P/N CAR401, except for airplanes on which Airbus Modification 201384 has been embodied during production, or on which Airbus Service Bulletin A330–29–3119 (for Model A330–200, –200F, and –300 series airplanes) or Airbus Service Bulletin A340–29–4091 (for Model A340–200 and –300 series airplanes) has been embodied in service: Within 900 flight hours after the effective date of this AD, inspect the check valves on the blue, green, and yellow hydraulic systems to identify their part numbers, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–29–3111, Revision 02, dated June 23, 2011 (for Model A330–200, –200F and –300 series airplanes); or Airbus Mandatory Service Bulletin A340–29–4086, Revision 02, dated June 23, 2011 (for Model A340–200 and –300 series airplanes). Accomplishment of the actions required by this paragraph terminates the requirements specified in paragraphs (g)(1) and (g)(1)(ii) of this AD.

(1) If check valves having P/N CAR401 are installed on all three hydraulic systems: Before further flight, do the inspection program (detailed inspection for red mark presence and alignment integrity of the check valve and manifold, a detailed inspection for traces of seepage or black deposits, and an inspection for proper torque) on yellow and blue high pressure manifolds, and do all applicable corrective actions, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–29–3111, Revision 02, dated June 23, 2011 (for Model A330–200, –200F, and –300 series airplanes); or Airbus Mandatory Service Bulletin A340–29–4086, Revision 02, dated June 23, 2011 (for Model A340–200 and –300 series airplanes). Accomplishment of the actions required by this paragraph terminates the requirements specified in paragraph (g)(2)(i) of this AD.

(2) If check valves having P/N CAR401 are not installed on all three hydraulic systems, no further action is required by this paragraph until any check valve having P/N CAR400 is replaced with a check valve having P/N CAR401. If any check valve having P/N CAR400 is replaced by a check valve having P/N CAR401: Before further flight after such replacement, do the actions specified in paragraph (h) of this AD, to determine if all three hydraulic systems are equipped with check valves having P/N CAR401. If check valves having P/N CAR401 are installed on all three hydraulic systems: Before further flight, do the actions specified in paragraphs (h)(1) and (i) of this AD.

(i) New Repetitive Inspection Program and Corrective Actions

Within 900 flight hours after accomplishment of paragraph (h)(1) of this AD, do the inspection program (detailed inspection for red mark presence and alignment integrity of the check valve and manifold, a detailed inspection for traces of seepage or black deposits, and an inspection for proper torque) on the green, yellow, and blue system check valves, and do all applicable corrective actions, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–29–3111, Revision 02, dated June 23, 2011 (for Model A330–200, –200F, and –300 series airplanes); or Airbus Mandatory Service Bulletin A340–29–4086, Revision 02, dated June 23, 2011 (for Model A340–200 and –300 series airplanes). Repeat the inspection program thereafter at intervals not to exceed 900 flight hours. Do all applicable corrective actions before further flight. Accomplishment of the actions required by this paragraph terminates the requirements specified in paragraphs (g)(1)(i), (g)(2)(ii), and (g)(2)(iii) of this AD.

(j) New Repetitive Inspection for Certain Airplanes

For airplanes equipped with check valves having P/N CAR401 and on which Airbus Modification 201384 has been embodied during production, or on which Airbus Service Bulletin A330–29–3119 (for Model A330–200, –200F, and –300 series airplanes);

or Airbus Service Bulletin A340–29–4091 (for Model A340–200 and –300 series airplanes) has been embodied in service: Within 1,000 flight hours after the effective date of this AD, do a general visual inspection of the green, yellow, and blue high pressure manifolds and check valves having P/N CAR401 for any sign of rotation of the check valve head, and for any signs of hydraulic fluid leakage or seepage (including black deposits), in accordance with the instructions of Airbus Alert Operators Transmission A29L001–12, dated October 11, 2012. Repeat the inspection thereafter at interval not to exceed 900 flight hours.

(k) New Corrective Action for Certain Airplanes

If, during any inspection required by paragraph (j) of this AD, any sign of rotation of the check valve head is found, or any sign of hydraulic fluid leakage or seepage (including black deposits) is found: Before further flight, do all applicable corrective actions, in accordance with the instructions of Airbus Alert Operators Transmission A29L001–12, dated October 11, 2012.

(l) No Terminating Action

Accomplishment of the corrective actions required by this AD does not constitute terminating action for the repetitive inspections required by this AD.

(m) Replacement Check Valve Torque Value

As of the effective date of this AD, at each replacement of a check valve with a check valve having P/N CAR401, apply a torque of 141 to 143 newton metre (N.m) (103.98 to 105.45 pounds-foot (lbf.ft)) during installation.

(n) Credit for Previous Actions

(1) This paragraph restates the credit specified in paragraph (g)(2)(iv) of AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009). This paragraph provides credit for actions required by paragraph (g)(2)(i) of this AD, if those actions were performed before December 14, 2009 (the effective date of AD 2009–24–09), using Airbus AOT A330–29A3111, dated September 2, 2009 (for Model A330–200 and –300 series airplanes); or AOT A340–29A4086, dated September 2, 2009 (for Model A340–200 and –300 series airplanes).

(2) This paragraph provides credit for actions required by paragraph (h) of this AD, if those actions were performed before the effective date of this AD using Airbus AOT A330–29A3111, dated September 2, 2009; or Revision 1, dated October 8, 2009 (for Model A330–200 and –300 series airplanes); or AOT A340–29A4086, dated September 2, 2009; or Revision 1, dated October 8, 2009 (for Model A340–200 and –300 series airplanes). After the effective date of this AD all inspections and corrective actions, as required by paragraph (i) of this AD, must be accomplished in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–29–3111, Revision 02, dated June 23, 2011, or Airbus Mandatory Service Bulletin A340–29–4086, Revision 02, dated June 23, 2011; as applicable.

(o) No Reporting

Although the service information specified in paragraphs (o)(1) through (o)(5) of this AD specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(1) Airbus Alert Operators Transmission A29L001–12, dated October 11, 2012.

(2) Airbus Mandatory Service Bulletin A330–29–3111, Revision 02, dated June 23, 2011.

(3) Airbus Mandatory Service Bulletin A340–29–4086, Revision 02, dated June 23, 2011.

(4) Airbus AOT A330–29A3111, Revision 1, dated October 8, 2009.

(5) Airbus AOT A340–29A4086, Revision 1, dated October 8, 2009.

(p) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1138; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD. AMOCs approved for AD 2009–24–09, Amendment 39–16068 (74 FR 62208, November 27, 2009) are approved as AMOCs for the corresponding provisions of this AD, except AMOC ANM–116–11–172 is not approved as an AMOC for the corresponding provisions of this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(q) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information European Aviation Safety Agency Airworthiness Directive 2012–0244R1, dated January 25, 2013; and the following service information; for related information.

(i) Airbus Alert Operators Transmission A29L001–12, dated October 11, 2012.

(ii) Airbus Mandatory Service Bulletin A330–29–3111, Revision 02, dated June 23, 2011.

(iii) Airbus Mandatory Service Bulletin A340–29–4086, Revision 02, dated June 23, 2011.

(iv) Airbus AOT A330–29A3111, Revision 1, dated October 8, 2009.

(v) Airbus AOT A340–29A4086, Revision 1, dated October 8, 2009.

(2) For service information identified in this AD, contact, Airbus SAS—Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *airworthiness.A330–A340@airbus.com*; Internet *http://www.airbus.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on April 26, 2013.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–10908 Filed 5–7–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0366; Directorate Identifier 2011–NM–024–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede an existing airworthiness directive (AD) that applies to certain The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–300, 747–400, 747–400D, and 747SR series airplanes. The existing AD requires, for certain airplanes, inspection to determine the material of a main entry door (MED) reveal; repetitive inspections of certain reveals for cracking; a detailed inspection of certain reveals for a sharp edge and cracking; and corrective action if necessary. That AD also allows a certain replacement as an optional action for certain inspections of certain airplanes. Since we issued that AD, an operator reported a crack found in a 6061 machined aluminum one-piece corner reveal. This proposed AD would add, for certain airplanes, an inspection to determine material type of MED reveals, repetitive inspections for cracking of 6061 machined aluminum one-piece corner reveals, and replacement with 6061 machined aluminum two-piece corner reveals if necessary. This

proposed AD would also allow replacement with two-piece corner reveals as an option for certain repetitive inspections. This proposed AD would also revise the applicability by removing a certain airplane. We are proposing this AD to detect and correct fatigue cracking of the lower forward corner reveal of the number 3 MEDs, which could lead to the door escape slide departing the airplane when the door is opened and the slide is deployed, and consequent injuries to passengers and crew using the door escape slide during an emergency evacuation.

DATES: We must receive comments on this proposed AD by June 24, 2013.

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

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

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Bill Ashforth, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: (425) 917–6432; fax: (425) 917–6590; email: *bill.ashforth@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2013–0366; Directorate Identifier 2011–NM–024–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

On August 20, 2008, we issued AD 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008), for certain The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–300, 747–400, 747–400D, and 747SR series airplanes. The existing AD requires, for certain airplanes, an inspection to determine the material of an MED reveal; repetitive inspections of certain reveals for cracking; a detailed inspection of certain reveals for a sharp edge and cracking; and corrective action if necessary. That AD also allows a certain replacement as an optional action for certain inspections of certain airplanes. The existing AD resulted from reports of cracking and/or a sharp edge in the lower forward corner reveal of the number 3 MEDs. We issued that AD to detect and correct fatigue cracking of the lower forward corner reveal of the number 3 MEDs, which could lead to the door escape slide departing the airplane when the door is opened and the slide is deployed, and possible consequent injuries to passengers and crew using the door escape slide during an emergency evacuation.

Actions Since Existing AD (73 FR 56960, October 1, 2008) Was Issued

Since we issued AD 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008), an operator reported a crack found in a 6061 machined aluminum one-piece corner reveal. Certain airplanes were equipped with either 356 cast aluminum or 6061 machined aluminum one-piece corner reveals at delivery. The existing AD allowed 356 cast aluminum reveals to be replaced with one-piece machined aluminum corner reveals. We have determined that inspections are necessary on airplanes having these one-piece reveals.

Relevant Service Information

AD 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008), referred to Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007, as the appropriate source of service information for the required actions. Boeing has since revised this service information.

We reviewed Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. No new airplanes were added to the effectivity of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, but airplane groups were changed based on the material composition of the corner reveals. This service information describes procedures for a material type inspection of one-piece or two-piece corner reveals; inspection for sharp edges and cracking; and replacement of reworked 356 cast aluminum corner reveals and 6061 machined aluminum one-piece corner reveals with 6061 machined aluminum two-piece corner reveals, which would eliminate the need for repetitive inspections.

Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, also specifies a revised effectivity that clarifies the cargo configuration exceptions by excluding airplanes modified to the Boeing converted freighter and large cargo freighter configurations and removing an exception for Groups 2 and 3 of airplanes modified to the special freighter configuration. This service information also removes line number (L/N) 1271, a Model 747–400F series airplane, from the effectivity because it is a freighter airplane.

FAA's Determination

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

Proposed AD Requirements

This proposed AD would retain all of the requirements of AD 2008–18–07, Amendment 39–15664 (73 FR 56960,

October 1, 2008). The proposed AD would require the actions specified in the service information described previously. The proposed AD would add, for certain airplanes, an inspection to determine material type of MED reveals, repetitive inspections for cracking of 6061 machined aluminum one-piece corner reveals, and replacement with 6061 machined aluminum two-piece corner reveals if necessary. This proposed AD would also allow replacement with two-piece corner reveals as an option for certain repetitive inspections. Also, the proposed AD would remove airplane L/N 1271, a Model 747–400F series airplane, from the AD applicability.

Changes To Existing AD (73 FR 56960, October 1, 2008)

This proposed AD would retain all of the requirements of AD 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008). However, we have removed the ''Service Bulletin Reference'' paragraph from this proposed AD. That paragraph was identified as paragraph (f) in AD 2008–18–07. That paragraph provided operators with a one-time citation of the referenced service bulletin in AD 2008–18–07. Instead, we have provided the full service bulletin citation throughout this proposed AD.

We have revised the heading and wording for paragraph (l) of this proposed AD, to clarify that the only exception to the procedures in Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; and Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010; is that, as of the effective date of this proposed AD, an operator's equivalent procedure may no longer be used without requesting approval of an alternative method of compliance (AMOC).

We have also re-designated Notes 1 and 2 of AD 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008), as paragraphs (p) and (q) of this proposed AD. This change does not affect the intent of those paragraphs.

Costs of Compliance

We estimate that this proposed AD affects 166 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Material type inspection and inspection for cracks (retained actions from AD 2008–18–07, Amendment 39-15664 (73 FR 56960, October 1, 2008)) (119 airplanes).	4 work-hours × $85 per hour = $340 per inspection cycle.	$0	$340 per inspection cycle.	$40,460 per inspection cycle.
New Material type inspection and inspection for cracks [new proposed action] (166 airplanes).	14 work-hours × $85 per hour = $1,190 per inspection cycle.	$0	$1,190 per inspection cycle.	$197,540 per inspection cycle.

We estimate the following costs to do any necessary on-condition actions that would be required based on the results of the proposed inspections. We have no way of determining the number of aircraft that might need these actions:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Corner reveal removal and replacement [new proposed action].	17 work-hours × $85 per hour = $1,445 per inspection cycle.	$9,525	$10,970 per inspection cycle.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing airworthiness directive (AD) 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008), and adding the following new AD:

The Boeing Company: Docket No. FAA–2013–0366; Directorate Identifier 2011–NM–024–AD.

(a) Comments Due Date

The FAA must receive comments on this AD action by June 24, 2013.

(b) Affected ADs

This AD supersedes AD 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008).

(c) Applicability

This AD applies to The Boeing Company Model 747–100, 747–100B, 747–100B SUD, 747–200B, 747–200C, 747–300, 747–400, 747–400D, and 747SR series airplanes, certificated in any category, as identified in Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, except airplanes that have been converted to an all-cargo configuration. The requirements of this AD also become applicable at the time when a converted airplane operating in an all-cargo configuration is converted back to a passenger or passenger/cargo configuration.

(d) Subject

Air Transport Association (ATA) of America Code 53: Fuselage.

(e) Unsafe Condition

This AD was prompted by a report of a crack found in a 6061 machined aluminum one-piece corner reveal. We are proposing this AD to detect and correct fatigue cracking of the lower forward corner reveal of the number 3 main entry doors (MEDs), which could lead to the door escape slide departing the airplane when the door is opened and the slide is deployed, and consequent injuries to passengers and crew using the door escape slide during an emergency evacuation.

(f) Compliance

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

(g) Retained Actions for Group 3 Airplanes

This paragraph restates the requirements of paragraph (g) of AD 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008), with revised service information. For airplanes identified as Group 3 airplanes in Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007: Before the accumulation of 10,000 total flight cycles, or within 1,000 flight cycles after November 5, 2008 (the effective date of AD 2008–18–07), whichever occurs later, do a detailed inspection for cracking of the lower forward corner reveals, in accordance with Part 8 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. As of the effective date of this AD, only Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, may be used to accomplish the actions required by this paragraph.

(1) If no cracking is found, repeat the inspection thereafter at intervals not to exceed 6,000 flight cycles until a new or reworked two-piece reveal is installed in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. As of the effective date of this AD, only Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, may be used to accomplish the actions required by this paragraph. No further action is required by this paragraph for that location only after the replacement.

(2) If cracking is found, do the replacement specified in paragraph (g)(2)(i) or (g)(2)(ii) of this AD.

(i) Before further flight, replace the reveal with a new or reworked two-piece reveal, in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. No further action is required by this paragraph for that location only after the replacement. As of the effective date of this AD, only Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, may be used to accomplish the actions required by this paragraph.

(ii) Before further flight, replace the reveal with a new or reworked one-piece machined aluminum reveal without a sharp edge, in accordance with Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 4 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. Before the accumulation of 10,000 flight cycles since new on the replacement reveal, do the inspection for cracking specified in Part 8 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. Repeat the inspection thereafter at intervals not to exceed 6,000 flight cycles until a new or reworked two-piece reveal is installed in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. If any cracking is found during any inspection required by this paragraph, before further flight, do the actions specified in paragraph (g)(2) of this AD. No further action is required by this paragraph for that location only after the replacement with a two-piece reveal. As of the effective date of this AD, only Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, may be used to accomplish the actions required by this paragraph.

(h) Retained Actions for Group 2 Airplanes

This paragraph restates the requirements of paragraph (h) of AD 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008), with revised service information. For airplanes identified as Group 2 airplanes in Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010: Before the accumulation of 1,500 total flight cycles, or within 1,000 flight cycles after November 5, 2008 (the effective date of AD 2008–18–07), whichever occurs later, do the inspection specified in paragraph (j) of this AD.

(i) Retained Actions for Group 1, Configuration 2 Airplanes

This paragraph restates the requirements of paragraph (i) of AD 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008), with revised service information. For airplanes identified as Group 1, Configuration 2 airplanes in Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010: Within 1,500 flight cycles after the lower forward corner reveal was last replaced, or 1,000 flight cycles after November 5, 2008 (the effective date of AD 2008–18–07), whichever occurs later, do the inspection specified in paragraph (j) of this AD.

(j) Retained Inspection for Cracking and Sharp Edge

This paragraph restates the requirements of paragraph (j) of AD 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008), with revised service information. At the applicable times specified in paragraphs (h) and (i) of this AD: Do a detailed inspection of the lower forward corner reveal for cracking and a sharp edge, in accordance with Part 5 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 1 and Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. As of the effective date of this AD, only Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, may be used to accomplish the actions required by this paragraph.

(1) If no cracking and no sharp edge are found, before the accumulation of 10,000 flight cycles on the lower forward corner reveal since new, or within 6,000 flight

cycles after doing the inspection required by paragraph (j) of this AD, whichever occurs later, do a detailed inspection for cracking, in accordance with Part 8 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. Inspect thereafter at intervals not to exceed 6,000 flight cycles, until a new or reworked two-piece reveal is installed in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. If any cracking is found during any inspection required by this paragraph, before further flight, do the actions specified in paragraph (j)(3) of this AD. No further action is required by this paragraph for that location only after the replacement with a two-piece reveal. As of the effective date of this AD, only Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, may be used to accomplish the actions required by this paragraph.

(2) If no cracking is found, but a sharp edge is found, do the actions specified in paragraph (j)(2)(i) or (j)(2)(ii) of this AD.

(i) Before further flight, replace the lower forward corner reveal with a new or reworked two-piece reveal, in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. No further action is required by this paragraph for that location only after the replacement. As of the effective date of this AD, only Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, may be used to accomplish the actions required by this paragraph.

(ii) Before further flight, replace the reveal with a new or reworked one-piece machined aluminum reveal without a sharp edge, in accordance with Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 4 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. Before the accumulation of 10,000 flight cycles on the replacement reveal since new, do the inspection for cracking, in accordance with Part 8 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. Inspect thereafter at intervals not to exceed 6,000 flight cycles, until a new or reworked two-piece reveal is installed in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. If any cracking is found during any inspection required by this paragraph, before further flight, do the actions specified in paragraph (j)(3) of this AD. No further action is required by this paragraph for that location only after the replacement with a two-piece reveal. As of the effective date of this AD, only Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, may be used to accomplish the actions required by this paragraph.

(3) If cracking is found, do the actions specified in paragraph (j)(3)(i) or (j)(3)(ii) of this AD.

(i) Before further flight, replace the reveal with a new or reworked two-piece reveal, in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. No further action is required by this paragraph for that location only after the replacement. As of the effective date of this AD, only Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, may be used to accomplish the actions required by this paragraph.

(ii) Before further flight, replace the lower forward corner reveal with a new or reworked one-piece machined aluminum reveal without a sharp edge, in accordance with Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 4 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. Before the accumulation of 10,000 flight cycles since new on the replacement reveal, do the inspection for cracking, in accordance with Part 8 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. Inspect thereafter at intervals not to exceed 6,000 flight cycles, until a new or reworked two-piece reveal is installed in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. If any cracking is found during any inspection required by this paragraph, before further flight, do the actions required by paragraph (j)(3) of this AD. No further action is required by this paragraph for that location only after the replacement with a two-piece reveal. As of the effective date of this AD, only Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, may be used to accomplish the actions required by this paragraph.

(k) Retained Actions for Group 1, Configuration 1 Airplanes

This paragraph restates the requirements of paragraph (k) of AD 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008), with revised service information. For airplanes identified as Group 1, Configuration 1 airplanes in Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007: Before the accumulation of 1,500 total flight cycles, or within 1,000 flight cycles after November 5, 2008 (the effective date of AD 2008–18–07), whichever occurs later, do a material type inspection to determine if the lower forward corner reveals are castings, in accordance with Part 1 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 6 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. As an alternative to the material type inspection, replacing a reveal with a new or reworked two-piece lower forward corner reveal, in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010; is terminating action for the requirements of this paragraph for that location only. As of the effective date of this AD, only Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, may be used to accomplish the actions required by this paragraph.

(1) If the forward corner reveal is not a casting: Before further flight, do the actions specified in paragraph (j) of this AD except for the inspection for a sharp edge.

(2) If the forward corner reveal is a casting: Before the accumulation of 7,000 total flight cycles, within 2,000 flight cycles after November 5, 2008 (the effective date of AD 2008–18–07), or within 3,000 flight cycles since the forward corner reveal was inspected as specified in Boeing Service Bulletin 747–53A2378, Revision 3, dated August 11, 2005; or Boeing Service Bulletin 747–53A2378, Revision 4, dated June 10, 2010; whichever occurs latest; do a detailed inspection for cracking of the lower forward corner reveal, in accordance with Part 1 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. As of the effective date of this AD, only Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, may be used to accomplish the actions required by this paragraph.

(i) If no cracking is found: Repeat the inspection specified in paragraph (k)(2) of this AD thereafter at intervals not to exceed 3,000 flight cycles until a new or reworked two-piece lower forward corner reveal is installed in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. No further action is required by this paragraph for that location only after the replacement.

(ii) If cracking is found: Do the actions specified in paragraph (k)(2)(ii)(A), (k)(2)(ii)(B), or (k)(2)(ii)(C) of this AD.

(A) Before further flight, weld repair the reveal, in accordance with Part 4 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 4 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. Repeat the inspection specified in paragraph (k)(2) of this AD thereafter at intervals not to exceed 3,000 flight cycles until a new or reworked two-piece reveal is installed in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. No further action is required by this paragraph for that location only after the replacement. As of the effective date of this AD, only Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, may be used to accomplish the actions required by this paragraph.

(B) Before further flight, replace the reveal with a new or reworked two-piece reveal, in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. No further action is required by this paragraph for that location only after the replacement. As of the effective date of this AD, only Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, may be used to accomplish the actions required by this paragraph.

(C) Before further flight, replace the reveal with a new or reworked one-piece machined aluminum reveal without a sharp edge, in accordance with Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 4 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. Before the accumulation of 10,000 flight cycles since new on the replacement reveal, do the inspection for cracking, in accordance with Part 8 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. Inspect thereafter at intervals not to exceed 6,000 flight cycles, until a new or reworked two-piece reveal is installed in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. If any cracking is found during any inspection required by this paragraph, before further flight, do the actions specified in paragraph (k)(2)(ii)(B) or (k)(2)(ii)(C) of this AD. No further action is required by this paragraph for that location only after the replacement with a two-piece reveal. As of the effective date of this AD, only Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, may be used to accomplish the actions required by this paragraph.

(l) Retained Requirement Regarding Operator's Equivalent Procedure

This paragraph restates the requirements of paragraph (l) of AD 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008). Although Step 5 of Figure 8 of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007, specifies that operators may accomplish the actions in accordance with ''an operator's equivalent procedure,'' this AD does not allow using an ''operator equivalent procedure unless approved as an alternative method of compliance in accordance with paragraph (w) of this AD.

(m) Retained Provisions for Compliance With AD 2007–12–11, Amendment 39–15089 (72 FR 31984, June 11, 2007), for MED 3 Only

This paragraph restates the provisions of paragraph (m) of AD 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008), with revised information. Accomplishment of the applicable repair required by AD 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008), constitutes compliance with the repair of the lower forward corner casting (reveal) of the number 3 MEDs only, as required by paragraph (q)(2)(ii) of AD 2007–12–11, Amendment 39–15089 (72 FR 31984, June 11, 2007), which specifies the actions must be done in accordance with Boeing Service Bulletin 747–53A2378, Revision 1, dated March 10, 1994; Boeing Service Bulletin 747–53A2378, Revision 3, dated August 11, 2005; or Boeing Service Bulletin 747–53A2378, Revision 4, dated June 10, 2010. As of the effective date of this AD, only Boeing Service Bulletin 747–53A2378, Revision 4, dated June 10, 2010, may be used to accomplish the actions specified in this paragraph. Accomplishment of the actions of this AD does not terminate the remaining requirements of AD 2007–12–11.

(n) Retained Parts Installation Prohibition (Cast 356 Aluminum) Reveals

This paragraph restates the requirement of paragraph (n) of AD 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008). As of November 5, 2008 (the effective date of AD 2008–18–07), no person may install a door lower forward corner reveal made of cast 356 aluminum on any airplane at a location specified by AD 2008–18–07.

(o) Retained Parts Installation Limitation (Machined 6061 Aluminum) Reveals

This paragraph restates the limitation specified by paragraph (o) of AD 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008), with revised service information. As of November 5, 2008 (the effective date of AD 2008–18–17), no person may install a door lower forward corner reveal made of machined 6061 aluminum on any airplane at a location specified by this AD, unless it has been confirmed/reworked to be without a sharp edge, in accordance with Part 5 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 1 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. As of the effective date of this AD, only Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, may be used to accomplish the actions required by this paragraph.

(p) Retained Optional Rework of One-Piece and Two-Piece Machined 6061 Aluminum Reveals

This paragraph restates the information provided in ''Note 1'' of AD 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008), with revised information. For the purpose of this AD, a one-piece machined 6061 aluminum reveal may be reworked into a two-piece reveal in accordance with the Accomplishment Instructions of the applicable service bulletin identified in paragraph of (p)(1) or (p)(2) of this AD, after it was verified to be crack free and without a sharp edge, or after it was confirmed to be crack free and reworked to remove a sharp edge. As of the effective date of this AD, only Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, may be used to accomplish the actions provided by this paragraph.

(1) Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007.

(2) Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010.

(q) Retained Optional Rework of One-Piece 6061 Aluminum Reveals With a Sharp Edge

This paragraph restates the information provided in ''Note 2'' of AD 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008), with revised service information. For the purpose of this AD, a one-piece machined 6061 aluminum reveal with a sharp edge may be reworked into a one-piece machined 6061 aluminum reveal without a

sharp edge, in accordance with Part 6 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 1 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010; after it is confirmed to be crack free in accordance with Part 5 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007, or Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. After the sharp edge is removed, the one-piece machined 6061 aluminum reveal without a sharp edge may be further reworked into a two-piece reveal, in accordance with Part 7 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Part 5 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. As of the effective date of this AD, only Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, may be used to accomplish the actions specified by this paragraph.

(r) New Actions for Previously Inspected Group 4 Airplanes: Corner Reveal Not Replaced, or Replaced With Two-Piece Reveal

For Group 4 airplanes identified in Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, that have been inspected previously in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; and on which the corner reveal either has not been replaced, or has been replaced with a two-piece reveal that was made by reworking an existing one-piece reveal: Before the accumulation of 7,000 total flight cycles, or within 3,000 flight cycles after the most recent inspection or rework done in accordance with Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010; or within 1,000 flight cycles after the effective date of this AD, whichever occurs latest; do a material type inspection to determine if the corner reveal is a casting, in accordance with Part 6 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. Doing the inspection specified in this paragraph terminates the inspections required by paragraph (j) of this AD for these airplanes.

(1) If, during any inspection required by paragraph (r) of this AD, any corner reveal is found to be a casting: Before further flight, do a detailed inspection for cracking of the corner reveal, in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010; and repeat the inspection thereafter at intervals not to exceed 3,000 flight cycles until a new two-piece reveal in installed in accordance with the requirements of paragraph (r)(1)(i) of this AD. If any cracking is found, do the actions specified in paragraph (r)(1)(i) or (r)(1)(ii) of this AD.

(i) Replace the cast reveal with a new 6061 machined aluminum two-piece corner reveal, before further flight, in accordance with Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010.

(ii) Repair all cracking, before further flight, in accordance with Part 4 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010.

(2) If, during any inspection required by paragraph (r) of this AD, any one-piece corner reveal is found to be installed and is not a casting: Before the accumulation of 10,000 total flight cycles; or within 6,000 flight cycles after the most recent inspection done in accordance with Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010; whichever occurs later; do a detailed inspection of the corner reveal for cracking, in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. Repeat the inspection for cracking thereafter at intervals not to exceed 6,000 flight cycles until the corner reveal is replaced with a 6061 machined aluminum two-piece corner reveal. If any cracking is found during any inspection required by paragraph (r)(2) of this AD, before further flight, replace the corner reveal with a 6061 machined aluminum two-piece corner reveal, in accordance with Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010.

(s) New Actions for Previously Inspected Group 4 Airplanes: Corner Reveal Replaced With One-Piece Reveal

For Group 4 airplanes identified in Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, that have been inspected previously in accordance with Boeing Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007, and on which the corner reveal has been replaced with a one-piece reveal: Within 10,000 flight cycles after the date the reveal was replaced with a one-piece corner reveal, do a detailed inspection for cracking of the corner reveal, in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. Repeat the inspection for cracking thereafter at intervals not to exceed 6,000 flight cycles until the corner reveal is replaced with a 6061 machined aluminum two-piece corner reveal, in accordance with the requirements of paragraph (u) of this AD. If any cracking is found during any inspection required this paragraph of this AD, before further flight, replace the one-piece corner reveal with a 6061 machined aluminum two-piece corner reveal, in accordance with Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010.

(t) New Actions for Group 4 Airplanes: Not Previously Inspected or Changed

For Group 4 airplanes identified in Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, that have not been previously inspected or changed in accordance with Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007: Before the accumulation of 1,500 total flight cycles, or within 1,000 flight cycles after the effective date of this AD, whichever occurs later, do a material type inspection to determine if the lower forward corner reveal is made from 6061 machined aluminum plate or 356 aluminum casting, in accordance with Part 6 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. Doing the inspection specified in this paragraph terminates the inspections required by paragraph (j) of this AD for these airplanes.

(1) If, during any inspection required by paragraph (t) of this AD, any corner reveal is found to be a casting: Before the accumulation of 7,000 total flight cycles; or within 2,000 flight cycles after the effective date of this AD; or within 3,000 flight cycles after the most recent inspection of the MED 3 corner reveal was done in accordance with Boeing Service Bulletin 747–53A2378, Revision 4, dated June 10, 2010; whichever occurs latest; do a detailed inspection for cracking of the corner reveal, in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. Repeat the inspection for cracking thereafter at intervals not to exceed 3,000 flight cycles until the corner reveal is replaced with a 6061 machined aluminum two-piece corner reveal. If any cracking is found during any inspection required by this paragraph of this AD, before further flight, replace the casting with a 6061 machined aluminum two-piece corner reveal, in accordance with Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010.

(2) If, during any inspection required by paragraph (t) of this AD, a corner reveal is found that is not a casting: Before further flight, do a detailed inspection for a sharp edge, in accordance with Part 1 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010; and do a detailed inspection for cracking of the corner reveal, in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. Repeat the inspection for cracking thereafter at intervals not to exceed 6,000 flight cycles until the corner reveal is replaced with a 6061 machined aluminum

two-piece corner reveal in accordance with the requirements of paragraph (u) of this AD.

(i) If any sharp edge is found during any inspection required by paragraph (t)(2) of this AD, before further flight, rework the corner reveal, in accordance with Part 1 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010.

(ii) If any cracking is found during any inspection required by paragraph (t)(2) of this AD, before further flight, replace the corner reveal with a 6061 machined aluminum two-piece corner reveal, in accordance with Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010.

(u) New Terminating Action for Repetitive Inspections

Installation of a 6061 machined aluminum two-piece corner reveal in accordance with Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, terminates the repetitive inspections required by paragraphs (r), (s), and (t) of this AD.

(v) Credit for Previous Actions

This paragraph provides credit for actions required by paragraphs (g) through (m) and (o) through (q) of this AD, if those actions were performed before the effective date of this AD using Boeing Special Attention Service Bulletin 747–53–2460, Revision 1, dated February 13, 2007; or Boeing Service Bulletin 747–53A2378, Revision 3, dated August 11, 2005; as applicable, which are not incorporated by reference in this AD.

(w) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD. Information may be emailed to: *9–ANM-Seattle-ACO-AMOC-REQUESTS@faa.gov.*

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) AMOCs previously approved in accordance with AD 2008–18–07, Amendment 39–15664 (73 FR 56960, October 1, 2008), are approved as AMOCs for the corresponding requirements of this AD for Group 2 and Group 3 airplanes identified in Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010. Previously approved AMOCs for Group 1 and Group 4 airplanes identified in Boeing Special Attention Service Bulletin 747–53–2460, Revision 2, dated December 22, 2010, are not approved for compliance with the actions required by this AD.

(x) Related Information

(1) For more information about this AD, contact Bill Ashforth, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: (425) 917–6432; fax: (425) 917–6590; email: *bill.ashforth@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on April 26, 2013.

Ali Bahrami,

Manager, Transport Aircraft Directorate, Aircraft Certification Service.

[FR Doc. 2013–10905 Filed 5–7–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2520

RIN 1210–AB20

Pension Benefit Statements

AGENCY: Employee Benefits Security Administration, Department of Labor.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Department of Labor (Department) is developing proposed regulations regarding the pension benefit statement requirements under section 105 of the Employee Retirement Income Security Act of 1974, as amended (ERISA). This advance notice of proposed rulemaking (ANPRM) describes certain rules the Department is considering as part of the proposed regulations. The rules being considered are limited to the pension benefit statements required of defined contribution plans. First, the Department is considering a rule that would require a participant's accrued benefits to be expressed on his pension benefit statement as an estimated lifetime stream of payments, in addition to being presented as an account balance. Second, the Department also is considering a rule that would require a participant's accrued benefits to be projected to his retirement date and then converted to and expressed as an estimated lifetime stream of payments. This ANPRM serves as a request for comments on specific language and concepts in advance of proposed regulations. The Department intends to consider all reasonable alternatives to direct regulation, including whether there is a way short of a regulatory mandate that will ensure that participants and beneficiaries get constructive and helpful lifetime income illustrations.

DATES: Comments are due on or before July 8, 2013.

ADDRESSES: You may submit comments, identified by RIN 1210–AB20, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: e-ORI@dol.gov.* Include RIN 1210–AB20 in the subject line of the message.
- *Mail:* Office of Regulations and Interpretations, Employee Benefits Security Administration, Room N–5655, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, Attention: Pension Benefit Statements Project.

Instructions: All submissions received must include the agency name and Regulation Identifier Number (RIN) for this rulemaking. Comments received will be posted without change to *http://www.regulations.gov* and *http://www.dol.gov/ebsa,* and made available for public inspection at the Public Disclosure Room, N–1513, Employee Benefits Security Administration, 200 Constitution Avenue NW., Washington, DC 20210, including any personal information provided. Persons submitting comments electronically are encouraged not to submit paper copies.

FOR FURTHER INFORMATION CONTACT: Suzanne Adelman or Tom Hindmarch at (202) 693–8500. This is not a toll free number.

SUPPLEMENTARY INFORMATION: This ANPRM has two main sections followed by Appendix A. The first section, entitled ''Background,'' contains the relevant statutory language on which the Department is basing the ANPRM and a discussion of the Department's general policy concern underlying the ANPRM. The second section, entitled ''Overview of Intended Regulations,''

presents questions, ideas, and potential language on certain rules the Department is considering as part of proposed regulations under section 105 of ERISA. Each of these sections has multiple subsections. Appendix A contains an example that demonstrates how to calculate a lifetime income illustration, using the regulatory framework in this ANPRM, for a hypothetical male participant, age forty-five, who has a spouse. In conjunction with the publication of this ANPRM, the Department also has made available on its Web site an interactive calculator that calculates lifetime income streams in accordance with such regulatory framework. This calculator is at *www.dol.gov/ebsa/regs/lifetimeincomecalculator.html*.

I. Background

A. Section 105 of ERISA

Section 105(a) of ERISA, as amended by section 508 of the Pension Protection Act of 2006 (Pub. L. 109–280), requires administrators of defined contribution plans to provide periodic pension benefit statements to participants and certain beneficiaries. 29 U.S.C. 1025(a). Benefit statements must be provided at least annually. If the plan permits participants and beneficiaries to direct their own investments, however, benefit statements must be provided at least quarterly. Section 105(a)(2) of ERISA contains the content requirements for benefit statements. Section 105(a)(2)(A)(i)(I) requires a benefit statement to indicate the participant's or beneficiary's ''total benefits accrued.'' The proposed rules being considered by the Department are pursuant to this section of ERISA, as well as ERISA section 505. Section 505, in relevant part, provides that the Secretary may prescribe such regulations as the Secretary finds necessary or appropriate to carry out the provisions of title I of ERISA. 29 U.S.C. 1135. Collectively, these provisions provide the authority on which the Department is considering a rule that would require a participant's ''total benefits accrued'' to be expressed as an estimated lifetime income stream of payments, in addition to being presented as an account balance.

B. General Policy Concern Being Addressed by This ANPRM

Workers today face greater responsibility for managing their assets for retirement, both while employed and during their retirement years. This greater responsibility is primarily a result of the trend away from defined benefit plans, where a worker's retirement benefit is typically a specified monthly payment for life, and toward defined contribution plans, where typically contribution, asset allocation, and drawdown decisions are assigned to the participant.[1] Managing finances in order to provide income for life for oneself and one's spouse is a tremendously difficult but important task. The rule under consideration by the Department would provide participants with information that the Department believes will ease the burden of this task.

Research suggests that people want to continue their current lifestyle after they retire and are concerned about having adequate precautionary savings for emergencies or illness.[2] Individuals may not understand, however, what savings, asset allocation, and drawdown decisions are necessary to achieve both of these goals. In particular, participants may have difficulty envisioning the lifetime monthly income that can be generated from an account balance.

In a comment letter to the Department, a national non-profit trade association of investment managers, consultants, recordkeepers, insurance companies, plan sponsors and others stated that ''[t]ranslating the amount saved into a future income estimate will serve to remind participants that their DC plan accumulations are needed to generate income throughout retirement. Additionally, when they see that $100,000 may only generate $700 of monthly income for life, the participant may be incented to save more aggressively.'' [3] The Department believes that expressing a participant's current and projected account balances as lifetime income streams would allow participants to make more informed retirement planning decisions. Recent research supports the hypothesis that providing participants with customized information on the decumulation phase can influence contribution behavior.[4]

In view of the importance of this issue, the Department and the Department of the Treasury, on February 2, 2010, published a request for information, entitled ''Request for Information Regarding Lifetime Income Options for Participants and Beneficiaries in Retirement Plans'' (RFI). See 75 FR 5253. As stated in the summary to the RFI, the Departments are reviewing the rules under ERISA and the plan qualification rules under the Internal Revenue Code of 1986 (Code) to determine whether, and, if so, how, the Departments could or should enhance, by regulation or otherwise, the retirement security of participants in employer-sponsored retirement plans and in individual retirement arrangements (IRAs) by facilitating access to, and use of, lifetime income or other arrangements designed to provide a lifetime stream of income after retirement. The RFI contained 39 questions on a wide array of subjects. The Department received in excess of 700 comments in response to the RFI. The Departments subsequently held a joint hearing on lifetime income options for retirement plans on September 14 and 15, 2010, in order to further consider several specific issues. Comments received in response to the RFI, written hearing testimony submitted to the Department, and the Department's official hearing transcripts are available on the Department's Web site at *www.dol.gov/ebsa/regs/cmt-1210-AB33.html*.

The RFI contained a section entitled ''Disclosing the Income Stream That Can Be Provided From an Account Balance.'' Within this section, the RFI contained the following questions relevant to this ANPRM:

21. Should an individual benefit statement present the participant's accrued benefits as a lifetime income stream of payments in addition to presenting the benefits as an account balance?

[1] The number of private defined benefit plans has fallen from just over 103,000 in 1975 to fewer than 48,000 in 2009 (a drop of over 50 percent in the last 34 years). The number of private defined contribution plans has grown from just over 207,000 in 1975 to almost 660,000 in 2009 (an increase of over 200 percent for the same time period). See Employee Benefits Security Administration, U.S. Department of Labor, *Private Pension Plan Bulletin Historical Tables and Graphs* (Mar. 2012), Table E1: Number of Pension Plans by type of Plan, 1975–2009, at *http://www.dol.gov/ebsa/pdf/historicaltables.pdf*.

[2] Some individuals may also want to leave bequests to their children and other heirs; however, the bequest motive may be less salient in retirement savings and spending decisions than other priorities. See Jonathan Skinner and Stephen P. Zeldes, *The Importance of Bequests and Life-Cycle Saving in Capital Accumulation: A New Answer,* American Economic Review 92(2): 274- 279 (May 2002) and Jeffrey R. Brown, Jeffrey R. Kling, Sendhil Mullainathan and Marian V. Wrobel, *Why Don't People Insure Late Life Consumption? A Framing Explanation of the Under-Annuitization Puzzle,* American Economic Review 98(2): 304–309 (May 2008).

[3] See comment no. 656 in response to the Department's Request for Information Regarding Lifetime Income Options for Participants and Beneficiaries in Retirement Plans. Comments are available on the Department's Web site at *www.dol.gov/ebsa/regs/cmt-1210-AB33.html*.

[4] See Goda, Gopi Shah, Colleen Flaherty Manchester, and Aaron Sojourner, ''What Will My Account Really Be Worth? An Experiment on Exponential Growth Bias and Retirement Saving,'' NBER Working Paper 17927, March 2012. See also *ACLI Retirement Choices Study,* Greenwald & Associates, April 2010 (Study revealed that 60 percent of respondents say that if the illustration of the participants' lifetime income generated by their retirement plan account would not be enough to meet their retirement needs, they would ''start saving more immediately.'')

22. If the answer to question 21 is yes, how should a lifetime stream of income payments be expressed on the benefit statement? For example, should payments be expressed as if they are to begin immediately or at specified retirement ages? Should benefit amounts be projected to a future retirement age based on the assumption of continued contributions? Should lifetime income payments be expressed in the form of monthly or annual payments? Should lifetime income payments of a married participant be expressed as a single-life annuity payable to the participant or a joint and survivor-type annuity, or both?

23. If the answer to question 21 is yes, what actuarial or other assumptions (*e.g.,* mortality, interest, etc.) would be needed in order to state accrued benefits as a lifetime stream of payments? If benefit payments are to commence at some date in the future, what interest rates (*e.g.,* deferred insurance annuity rates) and other assumptions should be applied? Should an expense load be reflected? Are there any authoritative tools or sources (online or otherwise) that plans should or could use for conversion purposes, or would the plan need to hire an actuary? Should caveats be required so that participants understand that lifetime income payments are merely estimates for illustrative purposes? Should the assumptions underlying the presentation of accrued benefits as a lifetime income stream of payments be disclosed to participants? Should the assumptions used to convert accounts into a lifetime stream of income payments be dictated by regulation, or should the Department issue assumptions that plan sponsors could rely upon as safe harbors?

After reviewing the responses to these questions, the Department agrees with those commenters who see a need to change the perception of retirement savings from simply a savings account to a vehicle for income replacement during retirement. Showing a participant the monthly retirement income he or she will receive from his or her retirement plan may help change that perception and, perhaps as suggested by many commenters, motivate workers to increase their savings.[5] We also understand from the commenters that, due to the broadening recognition of the importance of improving participants' retirement preparedness, a growing number of plans already provide a lifetime income illustration and often provide access to other lifetime income planning tools or retirement calculators.

Therefore, as part of the proposed regulations under section 105 of ERISA, the Department is considering the following ideas:

- A participant or beneficiary's pension benefit statement would contain that individual's current account balance. In addition, the current account balance would be converted to an estimated lifetime income stream of payments. The conversion illustration would assume the participant or beneficiary had reached normal retirement age under the plan as of the date of the benefit statement, even if he or she is much younger.
- For participants who have not yet reached normal retirement age, the pension benefit statement would show the projected account balance, as well as the lifetime income stream generated by it. A participant or beneficiary's current account balance would be projected to normal retirement age, based on assumed future contribution amounts and investment returns. The projected account balance would be converted to an estimated lifetime income stream of payments, assuming that the person retires at normal retirement age.
- Both lifetime income streams (*i.e.,* the one based on the current account balance and the one based on the projected account balance) would be presented as estimated monthly payments based on the expected mortality of the participant or beneficiary.[6] In addition, if the participant or beneficiary has a spouse, the lifetime income streams would be presented based on the joint lives of the participant or beneficiary and his or her spouse.
- Pension benefit statements would contain an understandable explanation of the assumptions behind the lifetime income stream illustrations. In addition, pension benefit statements would contain a statement that projections and lifetime income stream illustrations are estimates and not guarantees.

The Department anticipates that if pension benefit statements were to have these key features, participants and beneficiaries might be in a better position to assess their retirement readiness and to prepare for their retirement.[7] An illustration based on a person's current account balance will provide an immediate baseline to judge their present retirement readiness, *i.e.,* ''If I were old enough to retire today, this would be my monthly payment for life.'' An illustration based on a projected account balance will show, not what the participant has saved to date, but what he or she might realistically expect to have at retirement, *i.e.,* ''In twenty years, this could be my monthly payment for life at my current savings rate.''

II. Overview of Intended Regulations

This Overview section of the ANPRM presents questions, ideas, and potential language on certain rules the Department is considering as part of proposed regulations under section 105 of ERISA. The goal is to provide an early opportunity for interested stakeholders to provide advice and input into the policy development of future proposed regulations. This Overview section contains multiple subsections pertaining to the major issues raised in response to the RFI. This Overview section is followed by a regulatory framework and Appendix A. Appendix A provides an example of how to use the assumptions in the ANPRM's regulatory framework to calculate a projected account balance and convert the current and projected account balances into lifetime income streams.

A. Current and Projected Account Balances

Among those responding to the RFI, there are competing views as to whether a lifetime income illustration should be based on a participant's or beneficiary's current account balance or a projected account balance. While many commenters believe it is better to provide an illustration based on a current account balance, approximately the same number of commenters believes it is better to provide an illustration based on a projected account balance. A few commenters support both approaches.

Commenters who support using a participant's current account balance generally believe it is better and more helpful to base an illustration on what the participant *actually* has than on what the participant *may* have at some point in the future. They make the following observations. First, participants and beneficiaries will more readily understand illustrations based on actuality than on illustrations based on projections. Second, and related, a person is more likely to take some planning action if he understands the illustration. Third, because projections necessarily will be based on a number of assumptions (*e.g.,* future contributions and future investment returns), such projections are mere guesses and therefore likely to be

[5] Research also suggests that a small change in information presented on the benefit statement can have a significant impact on savings behavior. See Gopi Shah Goda, Colleen Flaherty Manchester, and Aaron Sojourner, *What Will My Account Really Be Worth? An Experiment on Exponential Growth Bias and Retirement Saving,* NBER Working Paper No. 17927 (March 2012) at *http://www.nber.org/papers/w17927.*

[6] The term ''expected mortality'' here refers to the probabilities in a mortality table, as opposed to life expectancy which is a single number that can be calculated from those probabilities.

[7] Lena Larsson, Annika Sundén, & Ole Settergren, *Pension Information: The Annual Statement at a Glance,* OECD Journal: General Papers, February 19, 2008 available at: *http://www.oecd.org/dataoecd/38/42/44509412.pdf.*

flawed. Fourth, because lifetime income illustrations are educational in nature, a static number at a point in time should be sufficient to meet that educational purpose. Fifth, illustrations based on current account balances may motivate participants and beneficiaries to save more if the monthly payments are small.

By contrast, those who support the use of projected account balances believe that an illustration based on a projection is actually more relevant and meaningful to a participant than an illustration based on that participant's current account balance, notwithstanding the inherent uncertainty in projecting an account balance. They make the following observations. First, at present it is common practice among financial planners to use projections when providing their clients with financial planning advice. Accordingly, if the Department's goal is to have pension benefit statements serve as a useful planning tool, then illustrations on benefit statements similarly should be based on projections. Second, projections may be based on assumptions, but not all assumptions are inherently flawed. Several commenters believe that the Department can establish reasonable parameters for assumptions, in order to avoid deception or abuse and increase the accuracy of projections. Third, there is no evidence that participants and beneficiaries necessarily will fail to comprehend a lifetime income illustration, or a projection, merely because it is based on assumptions, particularly where there are sufficient disclosures of the assumptions underlying the projections. Fourth, showing participants and beneficiaries the power of compound earnings may be a significant motivator to increase savings rates. Fifth, an illustration based on current account size simply has no relevance to a participant with decades to retirement age; and, in fact, such incomplete information may very well have the unintended consequence of discouraging savings and participation. Sixth, illustrations based on current balances may be considered flawed because account balances constantly change and, indeed, may change dramatically depending on market fluctuations.

The Department acknowledges the potential merit in both approaches. An illustration based on a participant's or beneficiary's current account balance could serve as an immediate benchmark for that participant because it would show the size of the monthly payment to expect if there were no further savings, gains or losses between now and retirement. It, in effect, shows participants and beneficiaries what they actually have, now, in the form of monthly payments. Although this type of benchmark is simplistic, the commenters may be right that it could motivate participants and beneficiaries to increase their savings rates now, especially if the participant or beneficiary perceives the monthly payment to be small relative to his or her current income needs. An illustration based on a participant or beneficiary's projected account balance, on the other hand, ordinarily will reflect larger monthly payments. The Department also agrees with those commenters who believe this methodology of framing benefits (*i.e.,* showing larger monthly payments than those based on a current account balance) may sufficiently motivate participants and beneficiaries to stay the course or even to increase their savings rates in order to increase their monthly amounts. Although the addition of necessary assumptions under this approach may create some additional uncertainty, this uncertainty can be mitigated somewhat by requiring that only reasonable assumptions be used in the calculations and appropriate cautions be included in the disclosure to participants and beneficiaries.

Accordingly, the Department is considering a proposal that generally would require pension benefit statements for all defined contribution plans to include the following information: (1) The value of the account balance as of the last day of the period covered by the statement (*i.e.,* ''current balance''), (2) a projected account balance, and (3) two lifetime income illustrations. The first lifetime illustration would be based on the participant's or beneficiary's current account balance, *i.e.,* the ''fair market value of the account balance as of the last day of the period covered by the statement.'' See ANPRM § 2520.105–1(c)(2)(v). The second lifetime income illustration would be based on a participant's or beneficiary's projected account balance, *i.e.,* ''the current dollar value of the projected balance at normal retirement age.'' See ANPRM § 2520.105(c)(2)(vi). To avoid confusion and unnecessary complication, the second illustration would not be required on any pension benefit statement on behalf of a participant who has reached normal retirement age under the plan as of the date of the benefit statement.

The presentation of this data on a participant's or beneficiary's benefit statement might look something like this:

Current Balance $125,000 Monthly Payment $625	Projected Balance $557,534 Monthly Payment $2,788

This shows both total balances (current and projected) and the monthly payments generated by each. The projected balance ($557,534) and related monthly payment ($2,788) would be discounted by an inflation factor in order to be shown in today's dollars. The reasoning behind this is that by removing inflation from the equation it will be easier for participants and beneficiaries to budget for their retirement years, today. For example, they can compare their projected monthly payments expressed in today's dollars with their current budget needs (*i.e.,* current consumption needs) and see how close they are to covering those needs. If there is an undesirable gap, they might increase their contributions. The Department invites comments on whether the projected balance and related monthly payment should be discounted for inflation. Many commenters on the RFI believe that projections should be presented in today's dollars in order to put future buying power into a meaningful context.

Many of the sample benefit statements reviewed by the Department show only the projected monthly payment expressed in today's dollars (the $2,788 figure in the example above), and not the discounted projected account balance (the $557,534 figure in the example above). The Department welcomes comments on whether it makes more sense to show *both* the discounted projected account balance ($557,534) and the resulting monthly payments ($2,788), or whether it is enough to show *only* the resulting monthly payments ($2,788).

All projections and lifetime income illustrations under consideration would be based on the participant's ''normal retirement age under the plan.'' See ANPRM § 2520.105–1(c)(2)(vi), (d)(1), (d)(2)(i) and (e)(4). Section 3(24) defines this as ''the earlier of—(A) the time a plan participant attains normal retirement age under the plan, or (B) the later of—(i) the time a plan participant attains age 65, or (ii) the 5th anniversary of the time a plan participant commenced participation in the plan.'' The Department is considering this date because it already is a significant date for ERISA purposes. However, this date could be a number of years before the participant or beneficiary is actually ready or able to retire from the workforce. A number of commenters suggested using the social security retirement age. Accordingly, the

Department specifically welcomes comments on whether the projection and lifetime income illustrations should use a date other than the normal retirement age, as defined in section 3(24) of ERISA, and if so what date and why. For example, comments could address the appropriateness of using age 65, social security retirement age (*e.g.,* currently age 66 or 67 depending upon the participant's birthdate), the minimum required distribution date (*e.g.,* age 71) or some other age.

The mechanics involved in projecting an account balance are discussed below in Section II.B of this document, entitled ''Methodology for Projecting an Account Balance.'' The mechanics involved in converting account balances into lifetime income streams are discussed in Section II.C of this document, entitled ''Methodology for Converting an Account Balance into a Lifetime Income Stream.''

B. Methodology for Projecting an Account Balance

As explained above, the Department is considering a proposed rule that would require a participant's or beneficiary's current account balance to be projected to his or her normal retirement age under the plan. This section of the ANPRM describes the standards, rules and assumptions being contemplated that plan administrators would have to follow when projecting participant and beneficiary account balances to retirement. In developing these standards, rules and assumptions, the Department believes it is important that: (1) Projections be meaningful to participants and beneficiaries, (2) projections not be overly burdensome for plan administrators to perform, and (3) any regulatory framework does not disturb current projection and illustration best practices or stifle innovation in this area.

Based on the RFI comments and the public hearing record, the Department understands the act of calculating a participant's projected account balance ordinarily would require consideration of the following five variables: (1) The participant's current account balance; (2) the number of years until the participant retires; (3) future contributions to the account (both employer and employee); (4) a rate of investment return; and (5) an inflation adjustment to convert the projected amount to today's dollars. The Department specifically requests comments on whether these are the appropriate variables that should be factored into the projections being considered by the Department. If not, why not, and are there other essential variables?

As explained in more detail below, the Department is considering a ''reasonableness'' standard as a general rule combined with a regulatory ''safe harbor.'' The general rule would permit a broad array of projection ''best practices'' to continue (which practices we assume meet the ''reasonableness'' standard), while the safe harbor would offer certainty for those plan administrators who seek that result or who do not currently provide projections. Plan administrators who follow the deterministic conditions of the safe harbor would have the comfort of knowing they have satisfied the primary elements of the general rule (*i.e.,* those elements of the general rule that otherwise would require discretionary activity of the plan administrator). In this regard, the safe harbor would be an option and not a regulatory requirement.

The general rule being considered by the Department is that ''projections shall be based on reasonable assumptions taking into account generally accepted investment theories.'' See ANPRM § 2520.105–1(d)(1). A projection will not be considered reasonable, however, ''unless it is expressed in current dollars and takes into account future contributions and investment returns.'' Id. Thus, the general rule being considered by the Department does not require any single method or single set of assumptions for projecting an account balance to normal retirement age, although it does require overall reasonableness in light of generally accepted investment theories. Nor does the general rule limit the specific factors that must be considered, although it does require consideration of at least future contributions, investment returns, and inflation.[8]

By contrast, the safe harbor being considered by the Department is narrower and more prescriptive than the general rule under consideration. The contemplated safe harbor would prescribe a specific set of assumptions for contributions, returns, and inflation.[9] The set of assumptions, when used together, would be considered per se reasonable for purposes of the general rule. Thus, by using the safe harbor assumptions together, plan administrators will be deemed to be in compliance with the portion of the general rule that requires them to take into account contributions, returns, and inflation when projecting account balances.

The first assumption is that ''contributions continue to normal retirement age at the current annual dollar amount, increased at a rate of three percent (3%) per year.'' [10] See ANPRM § 2520.105–1(d)(2)(i). A yearly contribution increase is included in this safe harbor assumption because many workers' contribution elections are expressed as a percentage of wages, and wages tend to increase over a worker's career due to raises, promotions, cost-of-living adjustments, and other factors. The Department is considering a whole number percentage (3%) in order to avoid giving participants and beneficiaries the false impression that account balance projections are exact.

The Department considers a 3% per year increase in wages to be a conservative assumption, and intentionally chooses a conservative assumption in this instance due to the wide variation of wage movement across workers. Some workers, particularly young workers, can expect their wages to rise at a rate higher than 3% per year. However, older workers often see wages increase no faster than the rate of consumer price inflation.[11] The Department believes that more harm would be done by overestimating wage

[8] The general rule is intended to provide plan administrators with flexibility to preserve current best practices regarding benefit statements and not stifle the development and innovation of technological tools in this area. For example, the general rule would permit plans that have online tools that employ stochastic modeling, such as retirement calculators and similar planning devices, to use the same technology to project account balances on pension benefit statements, provided that the projection methodology meets the reasonableness requirement in the general rule. A stochastic model is a tool for estimating probability distributions of potential outcomes by allowing for random variation in one or more inputs over time usually based on observed historical data for the selected inputs. Probability distributions of potential outcomes are derived from a large number of simulations (stochastic projections) which reflect the random variation in the input(s). The Department specifically welcomes comments on whether the general rule sufficiently facilitates the use of stochastic modeling for pension benefit statements. The Department also welcomes comments on other modeling or projection methods that might be appropriate for benefit statements and whether the general rule facilitates their use.

[9] Two of the five variables (current balance and years to retirement) are information known to the plan at the time the benefit statement is generated and, therefore, the safe harbor would not include assumptions pertaining to those variables.

[10] The assumed dollar amount (not the contribution percentage) would increase by a rate of 3% per year. For example, if contributions for year one were $10,000, the projected contributions would be $10,300 (1.03 × $10,000) for year two, $10,609 (1.03 × 10,300) for year three, and so forth.

[11] There is a large body of literature on age-earnings profiles which shows that workers' wages tend to increase rapidly when young, but at a rate similar to inflation at older ages. See, for example, Murphy, Kevin M. and Finis Welch, ''Empirical Age-Earnings Profiles,'' *Journal of Labor Economics,* Vol. 8, No. 2 (Apr. 1990), pp. 202–229.

increases for workers whose wages will remain flat than would be done by underestimating wage increases for workers whose wages are likely to rise quickly. The Department welcomes comments on this topic.[12]

The second and third assumptions are investment returns of seven percent (7%) per year (nominal) and a discount rate of three percent (3%) per year for establishing the value of the projected account balance in today's dollars. See ANPRM § 2520.105–1(d)(2)(ii) and (d)(2)(iii). As with the wage increase assumption, the Department is considering whole number percentages (7% and 3%) in order to avoid giving participants and beneficiaries the false impression that account balance projections are exact.

The 3% discount rate is included in the safe harbor to account for consumer price inflation (specifically inflation in the prices of goods that retirees consume). The Department is considering 3% because it reflects both historical inflation and expectations for future inflation. Since 1913, inflation has averaged 3.2% according to Consumer Price Index data from the Bureau of Labor Statistics. Furthermore, the trustees of the Social Security Trust Fund assume that cost of living adjustments (which are determined by the CPI–W) will average 2.8% between 2019 and 2086. Comments are specifically requested on these assumptions, taking into account the purpose for which these assumptions are being used.

Why a 7 percent rate of investment return assumption?

The 7% safe harbor assumption under consideration is based on historical market returns, actual returns derived by participants in 401(k) plans, and future return forecasts. The 7% rate is a nominal rate of return, which corresponds to an approximate 4% real return assuming 3% inflation in the future.[13] Again a round number is being considered in order to avoid giving participants and beneficiaries the false impression that projected future account balances are exact. The following analysis led the Department to this rate.

From 1996 to 2009, the share of 401(k) assets in equities varied from 56% to 76%.[14] In 2009, this total was approximately 60%. If beginning in 1926, 60% of assets were invested in an equity portfolio that mirrored the S&P 500 and 40% were invested in a bond portfolio and the assets were rebalanced at the beginning of each year without cost to preserve the 60/40 allocation, an investor would have averaged a 5.6% real return through 2010.[15]

However, it is unlikely that average investors would replicate this rate of return and more likely would achieve a lower real rate of return due, in part, to fees and transaction costs. For example, an asset weighted account analysis performed by the Investment Company Institute (ICI) indicates that 401(k) plan expense ratios average approximately 65 basis points.[16] Therefore, expense ratios alone would reduce the average real return to approximately 5%.[17] Average real returns also are reduced by transaction costs, including costs derived from turnover by the fund managers. According to ICI, the average dollar weighted turnover rate of 401(k) mutual fund holders is 43 percent. These transaction costs are not included in expense ratios.[18]

Turnover that occurs due to participants' management of their accounts also reduces average real returns. Some of these transactions represent poor timing of the markets, leading to further underperformance relative to buy-and-hold strategies. Academic literature suggests that participants often mistime their investments by pulling their money out of equities before periods of strong growth and investing more heavily in equities just before a market downturn, with load funds experiencing even worse mistiming.[19]

The measured disparity between the average annual returns that costless buy-and-hold strategies would generate and actual participant returns is consistent with recent Department statistics. Where a dollar invested in a 60/40 balanced fund with no transaction costs would have generated an 8.4% nominal return between 1990–2009, Department of Labor Form 5500 data indicate that large defined contribution plans achieved a nominal return of only 7.1% during the same period.[20]

Moreover, past return information, such as U.S. equity returns between 1926 and 2010, does not provide a sufficient basis for estimating future reasonable expected returns.[21] This was illustrated when the Department solicited peer review comments from economists in 2006 on the application of its Pension Simulation Model to assess the impact of its Qualified Default Investment Alternatives rule (QDIA) on pension savings. The commenters maintained that expected future U.S. equity returns are lower today than historic returns and will remain lower in the future. Based on these comments, the Department revised its initial real equity return assumption used to project future pension savings to approximately 4.9%.[22] Industry groups have reached similar conclusions. For example, as a follow up to a 1997 survey, a 2007 survey asked 400 finance professors to forecast what equity returns would be over the next 30 years; and the estimates were, on average, more than one percent below the 1997 results.[23]

For the reasons discussed above, which take into account historical market returns, actual returns derived

[12] See below for a discussion of historical and projected consumer price inflation.

[13] To be exact, it would correspond with 3.88% real returns.

[14] These estimates are based on Employee Benefit Research Institute/Investment Company Institute 401(k) plans surveys.

[15] Returns are based on Ibbotson data. The calculations were performed with the bond share of the portfolio being held either all in long-term corporate bonds (40 percent of total funds) or half in intermediate government bonds (20 percent of total funds) and half in long-term corporate bonds (20 percent of the total funds). The relative share made little difference. However, including riskier equities in the portfolio does matter. If 30% of assets were in small cap funds, 30% in an equity portfolio mirroring the S&P 500, and 40% in bonds, the returns would be approximately 1% larger.

[16] Sarah Holden, Michael Halladay, and Shaun Lutz, *The Economics of Providing 401(k) Plans: Services, Fees, and Expenses, 2010,* ICI Research Perspective, Vol. 17, No. 4 (June 2011).

[17] Returns are calculated as a geometric return $g=[(1+r_1)(1+r_2) \ldots (1+r_n)]^{(1/n)}$ where r_n=returns in the nth year.

[18] Holden, *supra* at footnote 16.

[19] Geoffrey C. Friesen and Travis Sapp, *Mutual Fund Flows and Investor Returns: An Empirical Examination of Fund Investor Timing Ability,* 31 Journal of Banking and Finance, 2796 (2007) available at SSRN: *http://ssrn.com/abstract=957728.* According to the article, the underperformance of investors due to poor timing is over 1.5% compared to what buy-and-hold strategies would have generated. The performance gap with buy and hold strategies due to poor investor timing is twice as large for load funds compared to non-load funds.

[20] The 8.4% returns are based upon Ibbotson data. The hypothetical fund would have 60 percent stocks, 20 percent long term corporate bonds and 20 percent intermediate government bonds. The portfolio would be rebalanced each year at no cost. *See* U.S. Department of Labor, Employee Benefits Security Administration, Private Pension Plan Bulletin Historical Tables and Graphs: 1975–2009, Table E21 (March 2012) at *http://www.dol.gov/ebsa/publications/form5500dataresearch.html#statisticalsummaries.*

[21] Ibbotson data begins in 1926.

[22] *See http://www.dol.gov/ebsa/regs/peerreview.html#section1.* These peer review comments were submitted to help inform the Department's Pension Simulation model that is used to forecast savings outlook for participants. Under the model, a portfolio consisting of 60% equity and 40% long-term government bonds would generate an approximate 7% nominal return.

[23] *See* Ivo Welch, *Views of Financial Economists on the Equity Premium and on Professional Controversies* 73 Journal of Business 501 (2000). *See also* Ivo Welch, *The Consensus Estimate for the Equity Premium by Academic Financial Economists in December 2008,* Social Sciences Research Network Paper No. 1084918, January 18, 2008 (last revised July 22, 2009) at *http://ssrn.com/abstract=1084918.*

by 401(k) plan participants, and future return forecasts, the Department believes that a 7% nominal return assumption (approximately 4% real return and 3% future inflation) is a reasonable rate of return assumption for plan administrators to use when calculating a future account balance at normal retirement age. However, the Department specifically is requesting comments on the appropriateness of this 7% investment return assumption.[24] Are there other valid approaches or data sources EBSA should consider in constructing a prospective safe harbor? Commenters are encouraged to keep in mind the Department's stated objectives (above) behind a projection requirement. Commenters not in favor of this safe harbor assumption are encouraged to provide empirical data supportive of alternative approaches.

Projections and Rules of the Financial Industry Regulatory Authority

National Association of Securities Dealers (NASD) Rule 2210(d)(1)(D), in relevant part, provides that ''[c]ommunications with the public may not predict or project performance, imply that past performance will recur or make any exaggerated or unwarranted claim, opinion or forecast''.[25] In response to questions regarding the relationship, if any, between the projection requirement under consideration by the Department and NASD Rule 2210(d)(1)(D) of the Financial Industry Regulatory Authority (FINRA), the Department and FINRA staff intend to work together and, if necessary, provide guidance, which may be similar to the guidance provided in connection with the Department's recently finalized participant-level fee disclosure regulation under 29 CFR 2550.404a–5.[26] The Department, therefore, is requesting comments on whether, and to what extent, such guidance is needed and why.

C. Methodology for Converting an Account Balance Into a Lifetime Income Stream

As explained above, in addition to a participant's or beneficiary's current and projected account balance, the Department is considering a requirement that each balance be expressed as a lifetime stream of income. Thus, each benefit statement ordinarily would contain two monthly estimated payment illustrations, one based on the current balance and a second based on a projected account balance.[27]

The commenters on the RFI identified two methods to convert an account balance to a stream of income in retirement. The first method was described as a ''draw down'' or ''systematic withdrawal'' approach. This method assumes the participant will withdraw each year a fixed dollar amount or a fixed percentage (*e.g.,* 4%) of the account until the account is gone. The commenters suggested that three, four or five percent per year might be reliable withdrawal rates for a participant who starts drawing down his account at age 65. The income stream illustrated under this approach would be the fixed dollar amount or fixed percentage, and could be shown as either monthly or annual payments. The second method is the annuitization approach. This approach, for example, expresses the benefit as a lifetime monthly payment to the participant similar in form to a pension payment made from a traditional defined benefit plan. This approach also is the method that insurance companies use to determine payment amounts with their annuity products.

The proposal the Department is considering would use the second method of conversion because, of the two approaches, the second method reflects ''lifetime'' income whereas the first method reflects an income stream that may or may not be payable for the life of the participant (*e.g.,* in the case of a participant who retires at age 65 and dies at age 94, a 4% draw down, assuming a constant zero rate of return, would exhaust the account in 25 years instead of life). The second method reflects one of the Department's primary goals in encouraging meaningful benefit statements—that plan participants and beneficiaries are informed of their financial readiness for the entirety of their retired lives, not just a portion of it.

According to the RFI commenters and others, there are five relevant factors that must be considered when illustrating or converting an account balance (whether current or projected) to a lifetime income stream. The first is the date the payments would start, often referred to as the ''annuity start date'' (ASD). The second is the age of the participant or beneficiary at the ASD. The third is the form of payment (*e.g.,* single life annuity). The fourth is the expected mortality of the participant or beneficiary and any spouse. The fifth is the interest rate for the applicable mortality period. The Department specifically requests comments on whether these are the appropriate variables for illustrating an account balance as a lifetime income stream. If not, why not, and are there other essential variables?

Each of the foregoing factors is addressed in ANPRM § 2520.105–1(e). For example, with respect to the form of payment, lifetime income illustrations would be based on level payments for the life of the participant or beneficiary. See ANPRM § 2520.105–1(e)(1)(i). If the participant or beneficiary is married, however, a second illustration would be required. This second illustration would be a level payment for the life of the participant based on the joint lives of the participant/beneficiary and spouse, with a fifty percent survivor's benefit to the surviving spouse. See ANPRM § 2520.105–1(e)(1)(ii). For this purpose, the plan may assume the spouse is the same age as the participant. Id.

The lifetime income illustrations being contemplated would assume that payments begin immediately and that

[24] In this regard, one idea the Department intends to explore further is the behavioral effects of this assumption and whether the assumption should be more conservative. As explained in the text above, the 7% expected future investment returns is an average. As such, it is neutral, meaning that individual participants may realize higher or lower returns. In 2010, over 22% of 401(k) participants had fewer than 40% of their 401(k) assets invested in equity, while 40% had over 80% of assets in equity. See Jack Van Derhei, Sarah Holden, Luis Alonso, and Steven Bass, *401(k) Plan Asset Allocation, Account Balances, and Loan Activity in 2010,* EBRI Issue Brief No. 366 (December 2011), Figure 30 at p. 29. Thus, a safe harbor assumption that is aimed at the average 401(k) participant would be out of line with the asset allocation of a majority of 401(k) participants. Participants with conservative asset allocations who, in fact, consistently generate returns lower than the 7% neutral rate assumption will see their projected balance decreasing year after year (even though contributions remain stable). What impact will a declining projected balance have on these participants? At least some literature suggests people dislike declining sequences. See George F. Loewenstein and Drazen Prelec, *Preferences for Sequences of Outcomes,* 100 Psychological Review 91 (1993). Would a more conservative safe harbor assumption (*e.g.,* risk-free return rate, which typically averages about 5% nominal (2% real) returns) have a more positive long-term effect than a neutral assumption on how participants and beneficiaries would view the lifetime income stream illustration and ultimately use it to aid their retirement planning?

[25] In March 2012, the SEC approved new FINRA rules governing communications with the public that will replace NASD Rule 2210. Under the new rules, which took effect in February 2013, a modified version of this provision will be found in FINRA Rule 2210(d)(1)(F). *See* FINRA Regulatory Notice 12–29 (June 2012) (announcing SEC approval of new FINRA communications rules).

[26] *See* FINRA Regulatory Notice 12–02 (January 2012) (providing guidance on application of communications rules to disclosures required by 29 CFR 2550.404a–5). *See also* SEC Staff No Action Letter (October 26, 2011) (agreeing to treat information provided by a plan administrator to participants required by and complying with disclosure requirements of section 404 of ERISA as if it were a communication that satisfies requirements of Rule 482 under the Securities Act of 1933).

[27] A projected account balance would not be required if the participant has reached normal retirement age under the plan. See ANPRM § 2520.105–1(c)(2)(vi).

the participant or beneficiary generally is normal retirement age under the plan (*e.g.,* 65 years old) even if the participant or beneficiary is much younger. For example, for a participant age 25 in a plan with a normal retirement age of 65, the assumed commencement date in a quarterly benefit statement that covered the period October 1, 2015 through December 31, 2015 would be January 1, 2016. See ANPRM § 2520.105–1(e)(4). In addition, the 25-year-old participant is assumed to be age 65 (*i.e.,* normal retirement age) on January 1, 2016. However, if the participant is older than normal retirement age, the plan administrator is required to use the participant's actual age.[28]

With respect to mortality and interest rate assumptions, many RFI commenters and others suggested that when a plan offers an annuity form of distribution, the actual mortality and interest rate provisions contained in the plan's annuity contract should be reflected in the lifetime income illustrations.[29] The Department agrees and intends to include this concept as part of the proposed regulation. See ANPRM § 2520.105–1(e)(3). However, for plans that do not offer annuity forms of distribution, the Department is considering a safe harbor approach for mortality and interest rate assumptions (similar to the safe harbor for the projection requirement set forth in ANPRM § 2520.105–1(d)). Specifically, the proposal would start with a general requirement that illustrations must be based on ''reasonable'' mortality and interest rate assumptions ''taking into account generally accepted actuarial principles.'' See ANPRM § 2520.105–1(e)(2)(i). This standard is intended to be flexible and to preserve current best practices, on the one hand, but protective on the other hand in that it would prohibit the use of assumptions that do not comport with generally accepted actuarial principles. Many commenters on the RFI requested some degree of flexibility in this area in order to match illustrations on benefit statements with illustrations provided through online tools. At the same time, however, other RFI commenters expressed concern with potential ERISA liability in connection with picking mortality and interest rate assumptions for lifetime income illustrations and strongly encouraged the Department to adopt safe harbor assumptions. Accordingly, the Department is considering the following safe harbor assumptions, each of which, when used together, would be deemed reasonable under the general requirements in ANPRM § 2520.105–1(e)(2)(i).

The safe harbor rate of interest under consideration is a ''rate of interest equal to the 10-year constant maturity Treasury securities rate, for the first business day of the last month of the period to which the statement relates.'' See paragraph (e)(2)(ii)(A). One commenter with members representing more than 90% of the assets and premiums in the U.S. life insurance and annuity industry stated that its members believe that the 10-year constant maturity Treasury rate best represents the interest rates that are reflected in actual annuity pricing. In addition, the 10-year constant maturity Treasury rate is published daily to the public and widely recognized.[30] The Department agrees that it may be helpful to participants to use a market rate that approximates what it actually would cost them to buy a lifetime income stream on the open market. In this regard, an illustration based on a current market rate would be especially beneficial for those participants or beneficiaries who are close to retirement, and less so for those farther from normal retirement age.[31]

The Department, however, is specifically requesting comments on whether the 10-year constant maturity Treasury rate assumption is the best interest rate assumption to use in this context, or whether there is a different interest rate or combination of rates that should be used, and why. For example, other RFI commenters mentioned that the Department might give some consideration to using the Pension Benefit Guaranty Corporation (PBGC) select and ultimate rates used to determine liabilities of terminated single-employer plans under section 4044 of ERISA which are published monthly by the PBGC[32] or the ''applicable interest rate'' under section 417(e)(3)(C) of the Code, although these commenters did not provide reasoning behind their suggestions. The commenter in favor of the 10-year constant maturity Treasury rate is concerned that the PBGC rates may not be sufficiently current for this type of illustration; or that such rates are not appropriate for pay out annuities. This commenter, in addition, is concerned that the Code section 417(e)(3)(C) rates, which it states are used for converting defined benefit amounts to a lump sum for distribution, do not approximate current annuity prices.

The safe harbor mortality assumption under consideration is ''the applicable mortality table under section 417(e)(3)(B) of the Code, in effect for the month that contains the last day of the period to which the statement relates.'' See ANPRM § 2520.105–1(e)(2)(ii)(B).[33] The section 417(e)(3)(B) applicable mortality table is a unisex table created and published by the Treasury Department.[34] The same commenter that suggested using the 10-year constant maturity Treasury rate also suggested using the section 417(e)(3)(B) applicable mortality table. Other commenters suggested the mortality

[28] If the participant has reached normal retirement age under the plan, the only illustration that would be required for this participant is the illustration based on his or her current account balance. An illustration based on a projected account balance would not be required in these circumstances. See ANPRM § 2520.105–1(c)(2)(vi).

[29] In 2010, 18 percent of private industry workers participated in a defined contribution retirement plan providing an option to take an annuity form of distribution at retirement. See Table 21a of U.S. Department of Labor, Bureau of Labor Statistics, ''National Compensation Survey: Health and Retirement Plan Provisions in Private Industry in the United States, 2010,'' Bulletin 2770, August 2011. Available at: *http://www.bls.gov/ncs/ebs/detailedprovisions/2010/ownership/private/table21a.pdf*

[30] See *www.federalreserve.gov/releases/h15/data.htm.*

[31] The Department recognizes that there is no single interest rate assumption that would be perfect for all participants. Those who will retire tomorrow and plan to purchase lifetime income will face pricing that reflects current interest rates. It is clear that for these participants, using an interest rate assumption based on current rates is appropriate. However, participants who are a substantial number of years away from retirement will be faced with annuity pricing that reflects future interest rates that are unknown. An appropriate way to project these future interest rates may be to use a long-term average of historical interest rates, with the belief that interest rates tend to revert to the mean. A third group of participants, those who will retire in a short number of years, are unique still from the other two groups. An example of an appropriate projection of interest rates at the time of retirement for these participants may be some combination of current and historical interest rates. In choosing a safe harbor assumption, the Department must consider all of these groups of participants and how their projections would be affected. For example, if the Department ultimately uses current interest rates as the safe harbor, movement in interest rates would be an additional source of variation in benefits statement projections year over year for participants who are a substantial number of years away from retirement.

[32] See 29 CFR 4044, Appendix B. See also *www.pbgc.gov/prac/interest/monthly.html.*

[33] The Department welcomes comments on the use of this month to determine the mortality, or whether it would be more appropriate to use the mortality table in effect for the month containing the assumed commencement date as defined in ANPRM § 2520.105–1(e)(4).

[34] Currently, the applicable mortality table is based on the Society of Actuaries, RP 2000 Mortality Tables Report at *http://www.soa.org/ccm/content/research-publications/experience-studies-tools/the-rp-2000-mortality-tables*, with a fixed blend of 50% of the static male combined mortality rates and 50% of the static female combined mortality rates promulgated under 26 CFR 1.430(h)(3)–1(c). See IRS Notice 2008–85, IRB 2008–42 which published unisex mortality tables for purposes of Code section 417(e)(3)(B) through 2013.

table used by the PBGC to determine the liabilities of terminated single-employer plans under section 4044 of ERISA.[35]

The Department selected the section 417(e)(3)(B) applicable mortality table for the following three reasons. First, the Treasury Department periodically updates the mortality table.[36] Second, unlike the PBGC mortality tables, the section 417(e)(3)(B) applicable mortality table is unisex.[37] Third, the table is publicly available and widely known to employee benefit plan service providers. The Department, however, is specifically requesting comments on whether the section 417(e)(3)(B) mortality table is the best mortality assumption to use in this context, or whether there is a different mortality assumption that should be used, and why. For example, one commenter suggested that if the plan did not provide an annuity option, the plan should be permitted to use gender based mortality tables in order to illustrate the dollar amount of a lifetime income stream which the participant or beneficiary could achieve if his or her account was rolled over into an individual retirement account and used to purchase a commercial annuity contract using gender based mortality.[38]

The rules and assumptions for converting current and projected account balances into lifetime income streams, discussed above and set forth in ANPRM § 2520.105–1(e), do not include an ''insurance load.'' In this context, the term ''insurance load'' is intended to describe the difference between the market price of lifetime income and the price of actuarially fair lifetime income. The insurance load may include insurance company profits, costs of insuring against systemic mortality risk, costs of holding cash reserves, advertising costs, the cost of selection (if not accounted for in the mortality table), and other operating costs. The Department specifically is requesting comments on whether a proposed rule should contain provisions requiring that such loads be factored into lifetime income streams and, if so, how should or could the rules and assumptions in ANPRM § 2520.105–1(e), including the safe harbor assumptions in ANPRM § 2520.105–1(e)(2)(ii), be modified to reflect such a requirement. For example, should the Department consider using a load assumption similar to the one used by the PBGC to determine the value of benefits for a single employer plan that has been involuntarily terminated and placed in trusteeship by the PBGC?[39]

D. Disclosure of Assumptions

Most of the commenters on the RFI indicated that the assumptions underlying any illustration should be disclosed to participants and beneficiaries. The Department agrees that clear disclosure of assumptions is needed for multiple reasons, but primarily in order to make it clear to participants and beneficiaries that projected amounts are not guarantees. The proposal under consideration, therefore, would require disclosure of any assumptions used in the benefit statement with regard to the projected account balance and the illustration of the lifetime income streams. See ANPRM § 2520.105–1(c)(6)(i) and (ii). In addition, the proposal would require that the pension benefit statement include a statement that the lifetime income stream is only an illustration and that actual periodic payments that may be purchased at retirement will depend on numerous factors and may vary substantially from the lifetime income stream illustration in the benefit statement. See ANPRM § 2520.105–1(c)(6)(iii). The Department is interested in comments on whether it would be helpful to participants and beneficiaries if their benefit statements explained that a consequence of purchasing an annuity outside of their pension plan is that gender-based mortality tables may be used and, if so, men will receive higher monthly payments and woman will receive lower monthly payments.

It is essential that assumption disclosures be written in manner calculated to be understood by the average plan participant. The Department, therefore, is interested in comments and suggestions on how best to achieve this result. For example, is there model language within the financial community or elsewhere that plan administrators could use to plainly explain or describe this information so as to increase its readability and understandability? Are there other formatting or presentation techniques relevant to this inquiry?

E. In-Plan Annuities

In addition to traditional distribution annuities, the Department is aware of the marketing and presence of in-plan annuity arrangements as investment options, sometimes generically referred to as ''incremental'' or ''accumulating'' annuities. According to the RFI commenters, these are arrangements that permit participants to make ongoing contributions toward the current purchase of a future stream of retirement income payments, which are guaranteed by an insurance company. Thus, conceptually, each contribution buys a small annuity. In this fashion, a participant has the ability to accumulate multiple small annuities over a career which, in the aggregate, could provide significant lifetime income.

More specifically, the RFI commenters explained that under these arrangements, typically, the ongoing participant contributions actually accumulate ownership units, that each such unit has a current market value, and that each unit will pay a fixed amount (usually per month) for the life of the owner commencing at retirement. For example, assume the current purchase price of a unit is $500 and each unit purchased will pay $15 per month, for life, commencing at retirement. A participant who has accumulated 100 units over his career will receive payments of $1,500 per month, for life, commencing at retirement. The RFI commenters further explain that although the current price of a unit ($500 in this example) fluctuates depending on a number of factors, such as the interest rate environment and the employee's age when the unit is purchased, the guaranteed monthly payment of each unit purchased (*e.g.,* $15 in this example) is fixed. RFI commenters also indicate that some products allow the participant to transfer out of the incremental annuity investment option and into another of the plan's designated investment alternatives, such as a mutual fund or other similar plan investment option, prior to normal retirement age or some other date (*e.g.,* the date distributions commence). The price per unit or pay out rate of an in-plan annuity with this transferability feature may differ from one without this feature.

The Department is soliciting comments on how best to factor investments of this type into lifetime income illustrations. For instance, one approach is that the current market

[35] See 29 CFR part 4044, Appendix A.

[36] The 417(e)(3)(B) mortality table is derived from the mortality tables prescribed under the funding rules of Code section 430(h)(3)(A) which states that the mortality tables prescribed by the Treasury Department ''shall be based on the actual experience of pension plans and projected trends in such experience . . . taking into account results of available independent studies of mortality of individuals covered by pension plans.''

[37] To the extent an individual account plan offers an annuity option, the mortality factors have to be the same for males and females to comply with *Arizona Governing Committee* v. *Norris,* 436 U.S. 1073 (1983).

[38] Since the female mortality tables show a longer life expectancy and the male mortality tables show a shorter life expectancy than a unisex table, the dollar amount of a male participant's monthly payment would be higher and a female participant's monthly payment would be lower in an illustration using gender based tables.

[39] See 29 CFR part 4044, Appendix C.

value of all in-plan annuity units accumulated by a participant could be added to the rest of that participant's account balance under ANPRM § 2520.105–1(c)(2)(v), before determining the projected account balance under ANPRM § 2520.105–1(c)(2)(vi).[40] A second approach is to add the total guaranteed monthly payment amount derived from all of a participant's in-plan annuity units to the estimated monthly payment amount of the non-annuity portion of the participant's account, if any, determined under ANPRM § 2520.105–1(c)(2)(vii) and (viii).[41] A third approach is to convert the participant's entire account balance, even any part that is not allocated to an in-plan annuity option, to a lifetime income stream using the current unit price of the in-plan annuity option.[42]

These three approaches are not necessarily the only options for incorporating the in-plan annuity values in lifetime income illustrations and the Department welcomes suggestions on other approaches. In this regard, commenters are encouraged to address whether, and to what extent, the language in ANPRM § 2520.105–1(e)(3) would need to be modified.[43] In addition, the Department welcomes the submission of actual benefit statements or similar documents showing how plans or insurance companies currently disclose in-plan annuity unit prices and monthly payment guarantees. Finally, given the wide array of ERISA plans and investment products, the Department also is soliciting comments on whether there are any foreseeable product-specific problems for products similar to in-plan annuities.

F. Miscellaneous

Many RFI commenters, hearing witnesses, and others who support lifetime income illustrations believe that the Department should take steps to encourage, rather than require, such illustrations on pension benefit statements. According to these individuals, mandating lifetime income illustrations would be expensive and may expose plan fiduciaries to litigation from plan participants and beneficiaries for a variety of reasons. The most commonly cited reason for potential lawsuits is unmet expectations. For example, if participants and beneficiaries during their working years mistakenly believe that the lifetime income illustrations on their pension benefit statements are promises or guarantees of a specific income stream, the participants and beneficiaries might sue if their actual account balances at retirement do not generate an income stream equal to or greater than the stream depicted in the illustrations in prior pension benefit statements.

The Department believes both concerns may be overstated. As to costs, first, some plans already provide lifetime income illustrations on pension benefit statements.[44] Thus, for these plans, there may be little if any additional cost associated with the ANPRM's regulatory framework. Second, pursuant to section 105 of ERISA, pension benefit statements already are required to include certain participant account information. Thus, for plans not already providing lifetime income illustrations on pension benefit statements, the Department does not believe that adding the lifetime income illustrations described above to these statements should significantly increase the cost of pension benefit statements.

The Department, however, specifically requests comments on the costs (and benefits) of including the illustration described herein in pension benefit statements. In this regard, the Department welcomes ideas on how the cost of the contemplated lifetime income illustrations might be reduced without compromising the anticipated benefits. For example, would there be substantial cost savings if illustrations were required only annually rather than quarterly? If yes, please explain why and quantify if possible. In addition, would there be substantial cost savings if the Department published (and periodically updated) a table of conversion factors based on the safe harbor assumptions contemplated in paragraph (e) of the ANPRM's regulatory framework? Such a table would make it possible to produce projections that satisfy the safe harbor with simple calculations and without the need to reference Treasury rates, mortality tables and other actuarial assumptions.[45] If yes, please explain why and quantify if possible. In addition, would there be substantial cost savings if all benefit statements were required to contain joint and survivor illustrations of the type described in ANPRM § 2520.105–1(e)(1)(ii), as opposed to including such illustrations only in benefit statements of married participants and beneficiaries? In other words, would there be cost savings in not having to track and determine marital status solely for pension benefit statement requirements? If yes, please explain why and quantify if possible.

As to the concern about potential lawsuits based on unrealized expectations, the Department believes this issue might be addressed in two ways. First, benefit statements could include a clear and definitive statement that the lifetime income illustration is an estimate, based on specific assumptions, and not a guarantee. The Department believes this disclosure would serve to put participants and beneficiaries on notice that the illustration is only an estimate and, thereby, minimize the likelihood that

[40] For example, assume a participant has $100,000 invested in certain of the plan's designated investment alternatives. Also assume that in addition to those investments, the participant also has 10 in-plan annuity units and that the current market value of a unit is $500. Under this approach, the participant's total account balance under ANPRM § 2520.105–1(c)(2)(v) would be $105,000, and the lifetime income illustrations would be based on this amount.

[41] For example, assume a participant has accumulated 100 units of an in-plan annuity and that each unit accumulated will pay $15 per month, for life, commencing at retirement. Thus, this participant will receive payments of $1,500 per month, for life, commencing at retirement based on these 100 units. Also assume this participant has a projected monthly payment of $2,500 based on investments in other designated investment alternatives under the plan (*e.g.,* mutual funds) using the safe harbor assumptions. Under this approach, the guaranteed monthly payment of the in-plan annuity ($1,500) could be added to the estimated monthly payment of $2,500, totaling $4,000 per month, for life.

[42] For example, assume a participant had accumulated 100 in-plan annuity units that each pay $15 per month, for life, commencing at retirement (totaling $1,500 per month). Also assume the participant had another $100,000 invested in other designated investment alternatives under the plan (such as mutual funds) and that the purchase price of a unit on the last day of the statement period is $500. Under this approach, the lifetime income illustration could be as if the participant had accumulated an additional 200 units with the $100,000 ($100,000/$500 = 200), totaling $3,000 per month in retirement income. Thus, the total estimated monthly payment under this approach would be $4,500 ($3,000 + $1,500) per month, for life.

[43] Paragraph (e)(3) provides that ''[i]f the plan offers an annuity form of distribution pursuant to a contract with an issuer licensed under applicable state insurance law, the plan shall substitute actual plan terms for the [safe harbor mortality and interest] assumptions set forth in paragraphs (e)(2)(ii)(A) and (B) of this section.''

[44] In one survey of large U.S. plan sponsors, 33% of respondents indicated that they provide retirement income projections to participants on benefit statements. See MetLife, ''Retirement Income Practices Study,'' June 2012 Located at: *https://www.metlife.com/retirementincomestudy.*

[45] For example, such a table would be based on the interest, mortality, and other assumptions selected by the Department and would contain factors for calculating a single life annuity and a joint and 50 percent survivor annuity. The relevant factor multiplied by the number of $1,000 increments comprising the participant's or beneficiary's total account balance would equal the monthly lifetime income stream. Assume, for example, that the participant has an account balance of $100,000 and the factor for single life annuity commencing at age 65 is 5.00 per thousand dollars. The $100,000 account balance would equate to a lifetime income stream of $500 per month ([$100,000 ÷ 1,000] × 5.00).

they would believe the illustration is a promise or guarantee. The Department specifically requests comments on the extent to which the language in ANPRM § 2520.105–1(c)(6) would accomplish this result. Second, the Department is considering establishing a regulatory safe harbor under section 105 of ERISA for plan administrators to rely on when developing lifetime income illustrations for pension benefit statements. By specifying the precise standards and assumptions a plan administrator would use to make a lifetime income illustration on a pension benefit statement, a regulatory safe harbor would substantially reduce the likelihood of lawsuits against that administrator based on an imprudent or improper calculation of lifetime income. See ANPRM § 2520.105–1(d)(2) and (e)(2)(ii). The Department specifically requests comments on the extent to which the regulatory safe harbor being considered would help address concerns about such potential lawsuits.

Furthermore, the Department has not concluded that the ANPRM's regulatory framework is the only or best approach. The Department intends to consider all reasonable alternatives to direct regulation, including whether there is a way short of a regulatory mandate to get plan administrators voluntarily to provide their participants and beneficiaries with constructive and helpful lifetime income illustrations. In developing the framework, the Department was mindful of the fact that administrators of defined contribution plans have been free to provide lifetime income illustrations to participants and beneficiaries for nearly 40 years since the enactment of ERISA, yet few actually have done so despite the apparent support for them evidenced by the vast majority of responsive RFI commenters and hearing witnesses who supported the concept. This ANPRM, nonetheless, solicits comments on all reasonable ideas, either in lieu of or in conjunction with a direct regulation, to address this very important issue. Commenters are encouraged to be specific with the responses and include data if possible to support their positions. The Department also welcomes the submission of sample benefit statements or similar documents currently being provided to participants and beneficiaries that include lifetime income illustrations.

List of Subjects in 29 CFR Part 2520

Annuity, Defined contribution plans, Disclosure, Employee benefit plans, Employee Retirement Income Security Act, Fiduciaries, Lifetime income, Pensions, Pension benefit statements, Plan administrators, Recordkeepers, Third party administrators.

For the reasons set forth in the preamble, the Department of Labor proposes to amend 29 CFR part 2520 as follows:

PART 2520—RULES AND REGULATIONS FOR REPORTING AND DISCLOSURE

■ 1. The authority citation for part 2520 is revised to read as follows:

Authority: 29 U.S.C. 1021–1025, 1027, 1029–31, 1059, 1134 and 1135; and Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012). Sec. 2520.101–2 also issued under 29 U.S.C. 1132, 1181–1183, 1181 note, 1185, 1185a–b, 1191, and 1191a–c. Sec. 2520.101–4 also issued under 29 U.S.C. 1021(f). Sec. 2520.101–6 also issued under 29 U.S.C. 1021(k) and Pub. L.109–280, § 502(a)(3), 120 Stat. 780, 940 (2006). Secs. 2520.102–3, 2520.104b–1 and 2520.104b–3 also issued under 29 U.S.C. 1003,1181–1183, 1181 note, 1185, 1185a–b, 1191, and 1191a–c. Secs. 2520.104b–1 and 2520.107 also issued under 26 U.S.C. 401 note, 111 Stat. 788. Sec. 2520.105–1 also issued under sec. 508(a) of Pub. L. 109–280, 120 Stat. 780.

2. Add § 2520.105–1 to subpart F to read as follows:

§ 2520.105–1 Periodic Pension Benefit Statements—Individual Account Plans.

(a) *[Reserved]*

(b) *[Reserved]*

(c) *Content requirements.* A benefit statement furnished under this section shall prominently display the beginning and ending dates of the period covered by the statement and contain the following information, based on the latest information available to the plan:

(1) [Reserved]

(2) *Total benefits accrued.*

(i)—(iv) [Reserved]

(v) The fair market value of the account balance as of the last day of the period covered by the statement;

(vi) If the participant has not reached normal retirement age as defined under the plan, the current dollar value of the projected account balance at normal retirement age determined in accordance with paragraph (d) of this section;

(vii) The amount specified in paragraph (c)(2)(v) of this section expressed as a lifetime income stream in accordance with paragraph (e) of this section; and

(viii) The amount specified in paragraph (c)(2)(vi) of this section expressed as a lifetime income stream in accordance with paragraph (e) of this section.

(3)–(5) [Reserved]

(6) *Explanation of lifetime income stream illustration.*

(i) Disclosure of the assumptions used pursuant to paragraph (d) of this section to establish the present value of the projected account balance required by paragraph (c)(2)(vi);

(ii) Disclosure of the assumptions used pursuant to paragraph (e) of this section to establish the lifetime income stream illustration required by paragraphs (c)(2)(vii) and (c)(2)(viii) of this section; and

(iii) A statement that the lifetime income stream illustrations required under paragraphs (c)(2)(vii) and (c)(2)(viii) of this section are illustrations only and that actual monthly payments that may be received at normal retirement age will depend on numerous factors and may vary from the illustrations in the benefit statement.

(d) *Rules and assumptions for projecting an account balance to normal retirement age.*

(1) *General.* For purposes of paragraph (c)(2)(vi) of this section (which sets forth the requirement to project a current account balance to normal retirement age under the plan), projections shall be based on reasonable assumptions taking into account generally accepted investment theories. A projection is not reasonable unless it is expressed in current dollars and takes into account future contributions and investment returns.

(2) *Safe harbor.* The following set of assumptions, when used together, are deemed reasonable for purposes of paragraph (d)(1) of this section:

(i) Contributions continue to normal retirement age at the current annual dollar amount, increased at a rate of three percent (3%) per year;

(ii) Investment returns are seven percent (7%) per year (nominal); and

(iii) A discount rate of three percent (3%) per year (for establishing the value of the projected account balance in current dollars).

(e) *Rules and assumptions for converting current and projected account balances into lifetime income streams.* For purposes of paragraphs (c)(2)(vii) and (c)(2)(viii) of this section—

(1) *Measuring lives.* A lifetime income stream shall—

(i) Be expressed as a level monthly payment, payable for the life of the participant beginning on the assumed commencement date, as defined in paragraph (e)(4) of this section;

(ii) If the participant is married, also be expressed as a level monthly payment, payable for the life of the participant beginning on the assumed commencement date, as defined in paragraph (e)(4) of this section, with a survivor's benefit, which is equal to fifty

percent (50%) of the monthly payment payable to the participant, payable for the life of the surviving spouse. For this purpose, it is permissible to assume the spouse is the same age as the participant; and

(iii) Be based on the assumptions set forth in paragraph (e)(2) of this section subject to the requirements in paragraph (e)(3) of this section.

(2) *Assumptions.*

(i) *General.* The interest and mortality assumptions behind a lifetime income stream shall each be reasonable taking into account generally accepted actuarial principles.

(ii) *Safe harbor.* The following assumptions are deemed reasonable for purposes of paragraph (e)(2)(i) of this section:

(A) A rate of interest equal to the 10-year constant maturity Treasury securities rate, for the first business day of the last month of the period to which the statement relates; and

(B) Mortality as reflected in the applicable mortality table under section 417(e)(3)(B) of the Internal Revenue Code, in effect for the month that contains the last day of the period to which the statement relates.

(3) *Plan terms.* If the plan offers an annuity form of distribution pursuant to a contract with an issuer licensed under applicable state insurance law, the plan shall substitute actual plan terms for the assumptions set forth in paragraphs (e)(2)(ii)(A) and (B) of this section.

(4) *Assumed commencement date.* For purposes of paragraph (e) of this section, the assumed commencement date shall be the first day following the period to which the statement relates, and the participant shall be assumed to be normal retirement age (as defined in section 3(24) of the Act) on this date (unless the participant is older than normal retirement age, in which case the participant's actual age should be used).

(f) [Reserved]

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

Appendix A

Lifetime Income Illustration

(a) *Purpose.* This Appendix A contains an example that illustrates the application of the safe harbor provisions set forth in ANPRM § 2520.105–1(d) and (e). The example is intended to aid the reader in understanding how the two safe harbors operate, independently and together, when calculating lifetime income streams based on current and projected account balances. The example is not intended as a model format or to provide model content for pension benefit statements, including the explanation for participants and beneficiaries required by ANPRM § 2520.105–1(c)(6).

(b) *Example: Facts.* Plan A is an individual account plan described in section 3(34) of the Act. Since the plan does not provide for the allocation of investment responsibilities to participants and beneficiaries, the plan is required to provide a benefit statement at least once each calendar year. The statement period and the plan year are the 2012 calendar year. Normal retirement age under the Plan is age 65. Participant P is age 45. His birth date is June 30, 1967. He is married. His account balance on December 31, 2012, the last day of the statement period, was $125,000. His contributions (employee and employer) for 2012 were $9,709. His contributions for 2013 are assumed to be $10,000 ($9,709 × 1.03). Contributions are assumed to be made on January 1 each year.

(c) *Safe harbor for projecting an account balance to normal retirement age.* Based on the safe harbor assumptions in ANPRM § 2520.105–1(d)(2) (as reflected in Table 1), the present value of the current balance ($125,000) projected to normal retirement age, as required by ANPRM § 2520.105–1(c)(2)(vi), is $557,534. P's December 31, 2012 account balance of $125,000 is projected to be $467,621 assuming a 7% return, compounded annually. Future contributions increasing at 3%, compounded annually with earnings at 7%, compounded annually, are projected to be $524,575 on June 30, 2032. P's aggregate projected account balance on June 30, 2032 is $992,196 ($467,621 + $524,575). The projected account balance of $992,196 discounted to December 31, 2012 at 3%, compounded annually, is $557,534.

TABLE 1

Normal Retirement Date	June 30, 2032.
Number of years in projection	19.5 (January 1, 2013 through June 30, 2032).
Number of contributions	19 ($10,000 per year adjusted by contribution increase rate) + 1 (final contribution of $5,000 in 2032, adjusted by contribution increase rate).
Paragraph (d)(2)(i) safe harbor—contribution increase rate	3% compounded annually.
Paragraph (d)(2)(ii) safe harbor—rate of return applied to current account balance of $125,000 and post 2012 projected contributions.	7% compounded annually.
Paragraph (d)(2)(iii) safe harbor-discount rate used to determine present value of the projected account balance.	3% compounded annually.

(d) *Safe harbor for converting current and projected account balances into lifetime income streams.* Based on the safe harbor assumptions in ANPRM § 2520.105–1(e)(2)(ii) (as reflected in Table 2), the lifetime income stream illustrations of the current and projected balances required by ANPRM § 2520.105–1(c)(2)(vii) and (c)(2)(viii), respectively, are set forth below. Using the assumptions in Table 2, the factor for converting a single sum into a level monthly payment for the life of P only (Single Life Form) is $5.00 per $1,000 of account balance. The factor for converting a single sum into a level monthly payment for the life of P with a 50% survivor benefit payable to P's spouse following his death (Joint and 50% Survivor Form) is $4.51 per $1,000 of account balance.

TABLE 2

Paragraph (e)(2)(ii)(A) safe harbor—10 year constant maturity Treasury rate on December 3, 2012:	1.63%, compounded annually.
Paragraph (e)(2)(ii)(B) safe harbor—Code section 417(e)(3)(B) applicable mortality table:	Unisex mortality table published in IRS Notice 2008–85.
Assumed commencement date	January 1, 2013.
Assumed Age of P on the assumed commencement date	65.
Assumed Age of P's spouse on the assumed commencement date	65 (*i.e.,* same as P).

Applying the factors described above to the December 31, 2012 current and projected account balances, the pension benefit statement would show the following lifetime income streams:

Account balance on last day of statement period (12/31/12)	Single life form (monthly payment for P's life with no survivor benefit)	Joint and 50% survivor form	
		Monthly payment during P's life	Monthly payment after P's death to surviving spouse
Current—$125,000	$625	$564	$282
Projected—$557,534	2,788	2,514	1,257

Signed at Washington, DC, this 17th day of April, 2013.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

[FR Doc. 2013–10636 Filed 5–7–13; 8:45 am]

BILLING CODE 4510–29–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2013–0358; FRL–9809–8]

Notice of Final Action on Petition From Earthjustice To List Coal Mines as a Source Category and To Regulate Air Emissions From Coal Mines

AGENCY: Environmental Protection Agency (EPA).

ACTION: Denial of petition for rulemaking.

SUMMARY: This action provides notice that on April 30, 2013, the Acting EPA Administrator, Bob Perciasepe, signed a letter denying a petition to add coal mines to the Clean Air Act (CAA) section 111 list of stationary source categories. The agency denied the petition because the EPA must prioritize its actions in light of limited resources and ongoing budget uncertainties, and at this time, cannot commit to conducting the process to determine whether coal mines should be added to the list of categories under CAA 111(b)(1)(A). The letter explains in detail the EPA's reasons for the denial.

FOR FURTHER INFORMATION CONTACT: Ms. Allison Mayer, Sector Policies and Programs Division (E143–03), Office of Air Quality Planning and Standards, Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–4016; fax number: (919) 541–3470; email address: *mayer.allison@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. How can I get copies of this document and other related information?

This **Federal Register** notice, the petition for rulemaking and the letter denying the petition for rulemaking are available in the docket that the EPA established under Docket ID Number EPA–HQ–OAR–2013–0358. All documents in the docket are listed on the *www.regulations.gov* Web site. Publicly available docket materials are available either electronically through *www.regulations.gov,* or in hard copy at the EPA Docket Center (Air 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 Docket is (202) 566–1742.

II. Judicial Review

Any petitions for review of the letter denying the petition to list coal mines as a source category described in this Notice must be filed in the Court of Appeals for the District of Columbia Circuit by July 8, 2013.

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations.

Dated: April 30, 2013.

Bob Perciasepe,

Acting EPA Administrator.

[FR Doc. 2013–10827 Filed 5–7–13; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 13–313; MB Docket No. 13–51; RM–11692]

Radio Broadcasting Services; Ehrenberg, Arizona

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a Petition for Rule Making filed by S and H Broadcasting, LLC, proposing the substitution of Channel 228C2 for vacant Channel 286C2 at Ehrenberg, Arizona. The proposed channel substitution at Ehrenberg accommodates the contingent hybrid application that requests the city of license modification for Station KRSX–FM, from Channel 287A, Twentynine Palms, California, to Channel 286A, North Shore, California. A staff engineering analysis indicates that Channel 228C2 can be allotted to Ehrenberg, Arizona consistent with the minimum distance separation requirements of the Commission's Rules with a site restriction located 11.1 kilometers (6.9 miles) east of Ehrenberg. In this regard, the Audio Division, on its own motion, modifies the reference coordinates for proposed Channel 228C2 at Ehrenberg, Arizona to the least restricted site. The reference coordinates are 33–36–54 NL and 114–24–14 WL. Channel 228C2 at Ehrenberg is located within 320 kilometers (199 miles) of the U.S.-Mexican border, so concurrence by the Government of Mexico is required. Mexican concurrence has been requested for this vacant allotment, but has not yet been received.

DATES: Comments must be filed on or before June 10, 2013, and reply comments on or before June 25, 2013.

ADDRESSES: Secretary, Federal Communications Commission, 445 12th Street SW., Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner as follows: Peter Gutmann,

Esq., Womble Carlyle Sandridge & Rice, LLP, 1200 19th Street NW., 5th Floor, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Rolanda F. Smith, Media Bureau, (202) 418–2700.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No.13–51, adopted April 18, 2013, and released April 19, 2013. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street SW., Washington, DC 20554. This document may also be purchased from the Commission's duplicating contractors, Best Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or via email *www.BCPIWEB.com.* This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

Federal Communications Commission.

Nazifa Sawez,

Assistant Chief, Audio Division, Media Bureau.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR Part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336 and 339.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Arizona, is amended by removing Channel 286C2 and by adding Channel 228C3 at Ehrenberg.

[FR Doc. 2013–10850 Filed 5–7–13; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 130312235–3235–01]

RIN 0648–BD04

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Snapper-Grouper Fishery Off the Southern Atlantic States; Regulatory Amendment 18

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes regulations to implement Regulatory Amendment 18 (Regulatory Amendment 18) to the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP), as prepared and submitted by the South Atlantic Fishery Management Council (Council). If implemented, this rule would update the annual catch limits (ACLs) for vermilion snapper and red porgy, modify the vermilion snapper commercial trip limit, and remove the recreational 5-month seasonal closure for vermilion snapper. The purpose of this rule is to help achieve optimum yield (OY) for snapper-grouper resources in accordance with the requirements of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

DATES: Written comments must be received on or before June 7, 2013.

ADDRESSES: You may submit comments on the proposed rule, identified by ''NOAA–NMFS–2013–0049'' by any of the following methods:

• *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2013-0049,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Submit written comments to Kate Michie, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

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

Electronic copies of the regulatory amendment, which includes an environmental assessment and an initial regulatory flexibility analysis (IRFA), may be obtained from the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Kate Michie, telephone: 727–824–5305, or email: *kate.michie@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South Atlantic is managed under the FMP. The FMP was prepared by the Council and is implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Act.

Background

The Magnuson-Stevens Act requires NMFS and regional fishery management councils to prevent overfishing and achieve, on a continuing basis, the OY from federally managed fish stocks. These mandates are intended to ensure that fishery resources are managed for the greatest overall benefit to the nation, particularly with respect to providing food production and recreational opportunities, and protecting marine ecosystems. To further this goal, the Magnuson-Stevens Act requires fishery managers to end overfishing of stocks and to minimize bycatch and bycatch mortality to the extent practicable.

Vermilion Snapper Stock Status

A Southeast Data, Assessment, and Review (SEDAR) stock assessment update for South Atlantic vermilion snapper was completed in October 2012 (SEDAR 17 update). SEDAR is organized

around three workshops. First is the data workshop, during which fisheries, monitoring, and life history data are reviewed and compiled. Second is the assessment workshop, where assessment models are developed and population parameters are estimated using the information provided from the data workshop. Third is the review workshop, where independent experts review the input data, assessment methods, and assessment products.

The SEDAR 17 update indicates vermilion snapper is not undergoing overfishing and is not overfished. Additionally, the SEDAR 17 update indicates the vermilion snapper biomass exceeds the target equilibrium biomass. This means that the acceptable biological catch (ABC) level and the ACL may be increased to allow for harvest of that excess biomass without jeopardizing the sustainability of the stock. Prior to the SEDAR 17 update, the last benchmark assessment for South Atlantic vermilion snapper was SEDAR 17 (2008), which indicated the stock was not overfished but was subject to overfishing as of 2007. SEDAR 17 included data through 2007 which was then updated in 2012 to include harvest information collected through 2011 (SEDAR 17 update).

The Comprehensive ACL Amendment (77 FR 15916, March 16, 2012) established an ABC control rule for assessed snapper-grouper species. In accordance with Magnuson-Stevens Act National Standard 1 guidelines, the ABC control rule takes into account scientific and data uncertainty that may exist for certain species managed within the snapper-grouper fishery management unit (FMU). The Comprehensive ACL Amendment established an ABC for vermilion snapper of 1,109,000 lb (503,034 kg), round weight. Using the ABC control rule and the results of the SEDAR 17 update, the Council's Scientific and Statistical Committee (SSC) recommended increasing the ABC for vermilion snapper to 1,372,000 lb (622,329 kg), round weight, for 2013; then decreasing the ABC to 1,312,000 lb (595,113 kg), round weight, for 2014; 1,289,000 lb (584,681 kg), round weight, for 2015; and 1,269,000 lb (575,609 kg), round weight, for 2016 and subsequent years. The ABC is gradually decreased over 3 years to allow for the harvest of excess biomass and is then held at a constant level when the population size reaches the equilibrium target level. The Council accepted the SSC's recommendation and, as discussed below, proposes to update the ACLs based on the new ABCs.

Red Porgy Stock Status

A SEDAR stock assessment update was completed for red porgy in October 2012 (2012 SEDAR 1 update). The objective of the 2012 SEDAR 1 update was to update the 2002 SEDAR 1 benchmark assessment and the 2006 SEDAR 1 update for red porgy.

The 2012 SEDAR 1 update includes additional data obtained since the 2006 SEDAR 1 update, and is based on information collected through 2011. The 2012 SEDAR 1 update indicates the red porgy stock is not undergoing overfishing but is still overfished; however, the 2012 SEDAR 1 update also indicates the stock is no longer rebuilding. All rebuilding projections performed in the 2012 SEDAR 1 update indicate that red porgy will not be rebuilt by the end of its rebuilding timeframe (2018). Therefore, the Council has requested a new benchmark assessment for the stock to be completed in 2014. After the new benchmark assessment is conducted, the Council may reconsider the rebuilding plan and modifications to management measures as necessary. However, until the new benchmark assessment is completed, Regulatory Amendment 18 would update the ABC, ACLs, annual catch targets (ACTs), maximum sustainable yield (MSY), and OY for red porgy based on the outcome of the 2012 SEDAR 1 update.

The National Standard 1 guidelines state that, for overfished stocks and stock complexes, a rebuilding ABC must be set to reflect the annual catch that is consistent with the schedule of fishing mortality rates in the rebuilding plan. Based on this guidance, the outcome of the 2012 SEDAR 1 update, and the ABC control rule established in the Comprehensive ACL Amendment, the SSC recommended a new ABC for red porgy that is lower than the current ABC of 395,304 lb (179,307 kg), round weight (landed catch). The ABC for red porgy would decrease to 306,000 lb (138,799 kg), round weight, for 2013; then increase to 309,000 lb (140,160 kg), round weight for 2014; and increase to 328,000 lb (148,778 kg), round weight for 2015. These ABC values are based on the yield at 75 percent of F_{MSY}. The Council accepted the SSC's recommendation and, as discussed below, proposes to update the ACLs based on the new ABCs.

Management Measures Contained in This Proposed Rule

This proposed rule would revise the commercial and recreational ACLs for vermilion snapper and red porgy, revise the vermilion snapper commercial trip limit, and remove the recreational closed season for vermilion snapper.

Vermilion Snapper ACLs

This proposed rule would increase the vermilion snapper ACLs based on the revised ABC values. Amendment 16 to the FMP (Amendment 16) established sector allocations for vermilion snapper of 68 percent for the commercial sector and 32 percent for the recreational sector (74 FR 30964, June 29, 2009). Additionally, Amendment 16 established two commercial fishing seasons for vermilion snapper. The first season is January through June, and the second is July through December.

Using on the SSC's ABC recommendation, the ACL formula established in the Comprehensive ACL Amendment where ABC = ACL = OY, and the allocation formula established through Amendment 16, the Council is proposing revised commercial and recreational ACLs for vermilion snapper. The commercial ACLs in round weight would be 932,960 lb (423,200 kg) in 2013; 892,160 lb (404,700 kg) in 2014; 876,520 lb (397,600 kg) in 2015; and 862,920 lb (391,400 kg) in 2016 and subsequent fishing years. The commercial ACLs would be further divided equally between the first and second commercial fishing seasons. The January through June and the July through December commercial ACLs would be 466,480 lb (211,592 kg), round weight (or 420,252 lb (190,623 kg), gutted weight) in 2013; 446,080 lb (202,338 kg), round weight (or 401,874 lb (182,287 kg), gutted weight) in 2014; 438,260 lb (198,791 kg), round weight (or 394,829 lb (179,091 kg), gutted weight) in 2015; and 431,460 lb (195,707 kg), round weight (or 388,703 lb (176,313 kg), gutted weight) in 2016 and subsequent fishing years.

The recreational ACLs, in round weight, would be 439,040 lb (199,145 kg) in 2013; 419,840 lb (190,436 kg) in 2014; 412,480 lb (187,098 kg) in 2015; and 406,080 lb (184,195 kg) in 2016 and subsequent fishing years. Any unused portion of the commercial ACL from the first part of the fishing year will be added to the commercial ACL for the second part of the fishing year.

Vermilion Snapper Commercial Trip Limit

Increasing the vermilion snapper ACLs would allow for increased harvest and increase the probability the commercial split seasons would be extended. However, even with a larger commercial ACL, in-season commercial closures are still expected. Therefore, this proposed rule would reduce the

commercial trip limit for vermilion snapper from 1,500 lb (680 kg), gutted weight, to 1,000 lb (454 kg), gutted weight (or 1,100 lb (503 kg), round weight). This rule proposes to reduce the commercial trip limit to 500 lb (227 kg), gutted weight (or 555 lb (252 kg), round weight) after 75 percent of the commercial ACL is reached or projected to be reached. Reducing the commercial trip limit and implementing a trip limit step down should help control the rate of commercial harvest and reduce the probability that either split season commercial ACL is exceeded.

Vermilion Snapper Recreational Seasonal Closure

This rule would remove the 5-month November through March recreational seasonal closure for vermilion snapper that was established in Amendment 16. This seasonal closure was implemented to address overfishing of the species (74 FR 30964, June 29, 2009). However, the SEDAR 17 update indicated that vermilion snapper is not overfished and is no longer undergoing overfishing. Further, an analysis conducted by NMFS indicates the recreational sector would likely harvest between 64 percent and 75 percent of the 2013 recreational ACL. Although the ACL would decrease slightly each year for the next several years, it is unlikely that the recreational vermilion snapper ACL would be met or exceeded in any given year in the near future. If the ACL is exceeded, Amendment 17B to the FMP implemented recreational AMs for vermilion snapper that would mitigate any ACL overage by reducing the recreational ACL for the following fishing year (75 FR 82280, December 30, 2010). Thus, no adverse biological impacts to the vermilion snapper resource are anticipated as a result of removing the seasonal closure.

In addition, in early 2013, the Southeast Fisheries Science Center (SEFSC) implemented a new electronic reporting system for headboats operating in the South Atlantic and Gulf of Mexico. The Gulf of Mexico Fishery Management Council and South Atlantic Council are currently developing amendments that would require federally permitted headboats to report all landings electronically at an increased frequency to the SEFSC. The SEFSC is also developing a similar program for charterboats. These improvements to the recreational harvest monitoring program are expected to increase the accuracy and timeliness of landings information, and help reduce the likelihood of recreational ACL overages.

Red Porgy ACLs

This proposed rule would reduce the commercial and recreational ACLs for red porgy. Currently, the red porgy stock ACL is equal to the ABC and is divided equally between the commercial and recreational sectors according to the formula established in the Comprehensive ACL Amendment. Based on the proposed stock ACL of 306,000 lb (138,799 kg), round weight, the commercial and recreational ACLs for red porgy, would be 153,000 lb (69,400 kg), round weight (or 147,115 lb (66,730 kg), gutted weight) in 2013; 154,500 lb (70,080 kg), round weight (or 148,558 lb (67,385 kg), gutted weight) in 2014; and 164,000 lb (74,389 kg), round weight, (or 157,692 lb (71,528 kg), gutted weight) in 2015 and subsequent fishing years.

Additional Management Measures Contained in Regulatory Amendment 18

Regulatory Amendment 18 also includes several actions that are not contained in this proposed rule. Based on the new ABCs, Regulatory Amendment 18 specifies a new maximum sustainable yield (MSY) and OY for vermilion snapper. Using the SEDAR 17 update results, the values for MSY and OY would be updated to incorporate the most recent harvest information for the stock. Regulatory Amendment 18 would also revise the OY to equal the ABC based on the SEDAR 17 update.

Additionally, Regulatory Amendment 18 would modify the current MSY and OY values for red porgy according to the new ABCs. The OY for red porgy would be equal to the ABC and the ACL as specified in the ACL formula established in the Comprehensive ACL Amendment. Regulatory Amendment 18 would also update the recreational ACT for red porgy based on the revised ABC using the ACT control rule established in the Comprehensive ACL Amendment. However, the recreational ACT is not included in the regulatory text, because it is a performance measure and not an actual limit on harvest.

The Council has requested that a new benchmark stock assessment for red porgy be conducted in 2014. Based on the outcome of the new benchmark assessment, the Council may decide to revise the rebuilding strategy and implement new management measures for the red porgy stock.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the Assistant Administrator has determined that this proposed rule is consistent with Regulatory Amendment 18, the FMP, Magnuson-Stevens Act and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

NMFS prepared an IRFA for this rule, as required by section 603 of the Regulatory Flexibility Act, 5 U.S.C. 603. The IRFA describes the economic impact that this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the objectives of and legal basis for this action are contained at the beginning of this section in the preamble and in the SUMMARY section of the preamble. A copy of the full analysis is available from the NMFS (see **ADDRESSES**). A summary of the IRFA follows.

The Magnuson-Stevens Act provides the statutory basis for this rule. No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting, record-keeping, or other compliance requirements are introduced by this proposed rule.

NMFS expects the proposed rule to directly affect commercial fishermen and for-hire vessel operators in the South Atlantic snapper-grouper fishery. The Small Business Administration established small entity size criteria for all major industry sectors in the U.S., including fish harvesters. A business involved in fish harvesting is classified as a small business if independently owned and operated, is not dominant in its field of operation (including its affiliates), and its combined annual receipts are not in excess of $4.0 million (NAICS code 114111, finfish fishing) for all of its affiliated operations worldwide. For for-hire vessels, all qualifiers apply except that the annual receipts threshold is $7.0 million (NAICS code 713990, recreational industries).

From 2007–2011, an annual average of 249 vessels with valid Federal permits to operate in the commercial snapper-grouper fishery landed at least 1 lb (0.4 kg) of vermilion snapper. These vessels generated dockside revenues of approximately $7.5 million (2011 dollars) from all South Atlantic species caught in the same trips as vermilion snapper, of which $3.1 million (2011 dollars) were from vermilion snapper. Each vessel, therefore, generated an average of approximately $30,000 in gross revenues, of which $12,000 were from vermilion snapper. For the same period, an annual average of 190 vessels

with valid Federal permits to operate in the commercial snapper-grouper fishery landed at least 1 lb (0.4 kg) of red porgy. These vessels generated dockside revenues of approximately $6.2 million (2011 dollars) from all species caught in the same trips as red porgy, of which $226,000 (2011 dollars) were from red porgy. Each vessel, therefore, generated an average of approximately $32,000 in gross revenues, of which $1,000 were from red porgy. Commercial vessels that operate in the vermilion snapper or red porgy components of the snapper-grouper fishery may also operate in other fisheries, the revenues of which are not reflected in these totals. Based on revenue information, all commercial vessels affected by the rule can be considered small entities.

From 2005–2010, an annual average of 1,985 vessels had valid Federal permits to operate in the for-hire component of the recreational sector of the snapper-grouper fishery. As of January 22, 2013, 1,462 vessels held South Atlantic for-hire snapper grouper Federal permits, and about 75 are estimated to have operated as headboats in 2013. The for-hire fleet consists of charter boats, which charge a fee on a vessel basis, and headboats, which charge a fee on an individual angler (head) basis. Average annual revenues (2011 dollars) per vessel for charter boats are estimated to be $126,032 for Florida vessels, $53,443 for Georgia vessels, $100,823 for South Carolina vessels, and $101,959 for North Carolina vessels. For headboats, the corresponding estimates are $209,507 for Florida vessels and $153,848 for vessels in the other South Atlantic states. Based on these average revenue figures, all for-hire operations that would be affected by the rule can be considered small entities.

NMFS expects the proposed rule will directly affect all federally permitted commercial vessels harvesting vermilion snapper or red porgy and for-hire vessels that operate in the South Atlantic snapper-grouper fishery. All directly affected entities have been determined, for the purpose of this analysis, to be small entities. Therefore, NMFS determined that the proposed action would affect a substantial number of small entities.

Because NMFS determined that all entities expected to be affected by the actions in this proposed rule are small entities, the issue of disproportional effects on small versus large entities does not arise in the present case.

The proposed vermilion snapper commercial and recreational ACLs would be set higher over the period 2013 through 2016, and in subsequent years, relative to the 2012 ACLs. This action would likely provide the commercial sector a longer fishing season that could result in higher industry revenues and possibly profits to commercial vessels. Relative to the 2012 commercial ACL, the proposed commercial ACL increases would generate additional ex-vessel revenues to commercial vessels. Based on past ex-vessel data applied to the increased ACLs, these additional revenues would be about $817,974 (2011 dollars) in 2013, and as the commercial ACL decreases to its lowest level in 2016 and subsequent years, the additional revenues would also be reduced to about $586,000 (2011 dollars).

The possibility of increased profits for commercial vessels from an increase in revenues would have to be balanced with the proposed lower vermilion snapper commercial trip limit. The trip limit, in conjunction with the increased commercial ACLs, is expected to extend the first commercial season by about 3½ weeks beyond the 2012 closure date, and the second season by about 3 weeks beyond the 2012 closure date. Before reaching 75 percent of the commercial ACL, the trip limit would benefit those who presently are harvesting less than 1,000 lb (454 kg), gutted weight, per trip, because it would allow them to continue to harvest that same amount per trip for an extended period and therefore generate more revenues and likely more profits for the entire fishing year. On the other hand, the trip limit would effectively increase the cost to the vessel per harvested fish of those already harvesting more than 1,000 lb (454 kg), gutted weight, per trip, although these fishermen could still take advantage of an extended season. A similar situation would occur once the trip limit is reduced to 500 lb (227 kg), gutted weight, but in this case the scaled down trip limit would be the reference point. If the extended season could bring in relatively higher ex-vessel prices, those not adversely affected by the commercial trip limit would very likely experience profit increases and those adversely affected by the trip limit would not necessarily experience profit reductions. Given this condition, it would appear that the net effects on vessel profits would be positive. However, many more vessels would be adversely affected once the trip limit of 500 lb (227 kg), gutted weight, takes effect. This limit could result in greater profit reductions to adversely affected vessels. The overall net effects of the commercial ACL increases and commercial trip limit reductions on vessel profits cannot be ascertained.

In principle, the proposed increase in vermilion snapper recreational ACL would benefit the for-hire vessels, but this result is highly dependent on whether the seasonal closure is eliminated. In recent years, the recreational sector has not fully reached its ACL, and this could be due to the November through March closure of the vermilion snapper recreational sector. Eliminating this seasonal closure would very likely increase the trips of for-hire vessels targeting vermilion snapper so that net operating revenues, or profits, of these vessels would also likely increase. An in-season recreational sector quota closure, however, would constrain any increases in the profits of for-hire vessels, but projections indicate that the recreational ACT are unlikely to be reached during the fishing year, at least in the short-term. It is, therefore, likely that the recreational ACL increases, in conjunction with the elimination of the seasonal closure, would result in profit increases for the for-hire vessels. Assuming that the recreational ACL would not be reached, and that there would not be an in-season quota closure, eliminating the recreational seasonal closure for vermilion snapper would increase the net operating revenues of charter boats by about $47,000 (2011 dollars) annually, and those of headboats by about $158,000 (2011 dollars) annually.

The proposed red porgy commercial and recreational ACLs for 2013 through 2015 would be lower than the current ACL so that, in principle, both commercial and for-hire vessels would be negatively affected. Since increasing the commercial ACL in 2009, the red porgy commercial sector has exceeded its ACL only once (in 2011), and in other years red porgy commercial landings were substantially lower than the sector's ACL. Based on a running average of commercial landings as a proxy for future landings, the proposed red porgy commercial ACLs for 2013 through 2015 are unlikely to be exceeded and therefore trigger an in-season closure of the commercial sector. Thus, unless there is a significant increase in commercial landings through a substantial increase in the stock size or fishing effort, the proposed commercial ACLs would likely not reduce the landings, revenues, and profits of commercial vessels. In the event the commercial ACLs are reached but not exceeded, commercial vessels could generate additional revenues from the proposed commercial ACLs. Relative to the landings and revenues in 2012 and assuming the commercial ACLs are reached, additional revenues

(2011 dollars) to commercial vessels would be approximately $259,000 in 2013, $261,000 in 2014, and $277,000 in 2015 and thereafter.

Recreational landings of red porgy have remained at very low levels, averaging approximately 110,000 lb (49,941 kg), round weight, annually from 2007 through 2011. In 2012, recreational landings of approximately 137,000 lb (62,199 kg), round weight, were less than 30 percent of the recreational sector's ACL. Therefore, the proposed recreational ACL would most likely have no effects on the profits of for-hire vessels, at least in the short-term. The long-term effects on profits depend on whether for-hire vessel trips targeting red porgy substantially increase. If such an increase in for-hire vessel trips did occur, for-hire profits would also increase.

The following discussion analyzes the alternatives that were not preferred by the Council, or alternatives for which the Council chose the no action alternative.

Two alternatives, including the preferred alternative, were considered for revising the vermilion snapper commercial and recreational ACLs. The only other alternative is the no action alternative, which would maintain the ACLs at a lower level than the proposed sector ACLs. Selecting the no action alternative would lead to forgone profit increases for commercial and for-hire vessels that would otherwise be realized under the preferred alternative.

Three alternatives, including the preferred alternative, were considered for revising the commercial trip limit for vermilion snapper. The first alternative, the no action alternative, would maintain the trip limit at 1,500 lb (680 kg), gutted weight, which would be higher than that in the preferred alternative. Although, in principle, this alternative would have no effects on commercial vessel profits, there would be a higher probability of an ever-shortening commercial season, thereby adversely affecting the profits of many commercial vessels. The second alternative is a trip limit of 1,000 lb (454 kg), gutted weight, the same as the preferred alternative, but without the step down to a to 500 lb (227 kg), gutted weight, trip limit when 75 percent of the commercial ACL has been met or is projected to be met. This alternative would result in a shorter first and second commercial fishing seasons than the preferred alternative. As with the preferred alternative, it would increase the cost per landed fish of those already harvesting above the trip limit, although those vessels could increase their overall revenues by taking more fishing trips during the extended commercial season. The net effect on their profits would be positive only if ex-vessel prices substantially improved during the extended season. However, those vessels currently landing below the commercial trip limit would likely experience increased revenues and likely profits due to the extended season. As with the preferred alternative, this alternative's overall net effects on the profits of commercial vessels cannot be ascertained. It is only noted that this alternative would adversely affect fewer vessels than the preferred alternative. Considering, however, that the commercial sector has been reaching its ACL in recent years, this alternative would have a higher probability of allowing overages to occur than the preferred alternative. Overages of the commercial ACL could lead to overfishing of vermilion snapper which would necessitate more restrictive measures that could, in turn, reduce the future revenues and profits of commercial vessels.

Two alternatives, including the preferred alternative, were considered for modifying the recreational closed season for vermilion snapper. The only other alternative is the no action alternative, which would maintain the November through March closure of the recreational sector for vermilion snapper. This alternative would lead to forgone for-hire vessel profits that would otherwise be realized with the preferred alternative.

Three alternatives, including the preferred alternative, were considered for revising the commercial and recreational ACLs for red porgy. The first alternative, the no action alternative, would retain the current ACL, which would be higher than the ACLs under the preferred alternative. Although this alternative would, in principle, provide for better profitability prospects for both the commercial and for-hire vessels, its effects in the short-term would be equivalent to those of the preferred alternative because, based on historical landings through 2012, the commercial and recreational landings would likely be lower than the proposed commercial and recreational ACLs. The second alternative is similar to the preferred alternative, except that it would set the sector ACLs for 2013 through 2018 and subsequent years until modified. The effects of this alternative on commercial and for-hire vessels would be identical to those of the preferred alternative for 2013 through 2015. In 2016 through 2018, this alternative would provide for higher sector ACLs and thus, in principle, would provide commercial vessels a better environment for generating higher revenues and profits. Assuming the commercial sector fully reaches its annual ACL in 2016 through 2018, this alternative would allow for additional revenues of about $127,000 (2011 dollars) over the preferred alternative for the three-year period (2016–2018). However, using a running average of commercial landings through 2012 as a proxy for future landings, the commercial ACLs under this alternative would likely not be reached. Therefore, the effects of this alternative on commercial vessels are virtually identical to those of the preferred alternative for the 3-year period (2016–2018). This alternative and the preferred alternative would most likely have identical effects on for-hire vessels in 2016 through 2018. Recreational landings of red porgy have stayed at very low levels, making it unlikely that the recreational ACLs under this alternative or the preferred alternative would be reached. The Council will receive a new benchmark stock assessment for red porgy in 2014. As described in Regulatory Amendment 18, these assessment results will be considered by the Council in 2015, and any necessary changes to the ACLs or other and management measures will be developed during 2015 with possible implementation in 2016. Hence the ACLs for 2016 and beyond may be revised based on the best scientific information available at that time.

The Council also considered two alternatives to modify the commercial fishing season for vermilion snapper, from which they selected the no action alternative. The no action alternative would maintain the split of the commercial fishing year, with January through June as the first season and July through December as the second season. This alternative would split the commercial ACL between the two seasons.

The second alternative consists of two sub-alternatives. The first sub-alternative would split the commercial fishing year into January through May as the first season and June through December as the second season. The second sub-alternative would split the commercial fishing year into January through April as the first season and May through December as the second season. In both sub-alternatives, the commercial ACL would be split equally between the two seasons. The Council noted the complexity of this action and decided to move it to Regulatory Amendment 14 to the FMP for consideration with possible additional alternatives. The timing of the opening and closure of the season for vermilion

snapper can impact the seasons for other snapper-grouper species, particularly the shallow-water grouper complex and black sea bass. The Council decided that a different amendment that would jointly consider the fishing season for vermilion snapper and black sea bass was the better approach. As a result of that decision, completion of Regulatory Amendment 18 would not be delayed by the consideration of a broader set of actions within the amendment, thus allowing the realization of more socioeconomic benefits from increased ACLs for vermilion snapper.

List of Subjects in 50 CFR Part 622

Fisheries, Fishing, Puerto Rico, Reporting and recordkeeping requirements, Virgin Islands.

Dated: May 2, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is proposed to be amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

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

§ 622.183 [Amended]

■ 2. In § 622.183, paragraph (b)(4) is removed and reserved.

■ 3. In § 622.190, introductory paragraph (a), and paragraphs (a)(4) and (a)(6) are revised to read as follows:

§ 622.190 Quotas.

* * * * *

(a) *South Atlantic snapper-grouper, excluding wreckfish.* The quotas apply to persons who are not subject to the bag limits. (See § 622.11 for applicability of the bag limits.) The quotas are in gutted weight, that is eviscerated but otherwise whole, except for the quotas in paragraphs (a)(4), (a)(5), and (a)(6) of this section which are in both gutted weight and round weight.

* * * * *

(4) *Vermilion snapper*—(i) For the period January through June each year.

(A) For the 2013 fishing year—420,252 lb (190,623 kg), gutted weight; 466,480 lb (211,592 kg), round weight.

(B) For the 2014 fishing year—401,874 lb (182,287 kg), gutted weight; 446,080 lb (202,338 kg), round weight.

(C) For the 2015 fishing year—394,829 lb (179,091 kg), gutted weight; 438,260 lb (198,791 kg), round weight.

(D) For the 2016 and subsequent fishing years—388,703 lb (176,313 kg), gutted weight; 431,460 lb (195,707 kg), round weight.

(ii) For the period July through December each year. (A) For the 2013 fishing year—420,252 lb (190,623 kg), gutted weight; 466,480 lb (211,592 kg), round weight.

(B) For the 2014 fishing year—401,874 lb (182,287 kg), gutted weight; 446,080 lb (202,338 kg), round weight.

(C) For the 2015 fishing year—394,829 lb (179,091 kg), gutted weight; 438,260 lb (198,791 kg), round weight.

(D) For the 2016 and subsequent fishing years—388,703 lb (176,313 kg), gutted weight; 431,460 lb (195,707 kg), round weight.

* * * * *

(6) *Red porgy*—(i) For the 2013 fishing year—147,115 lb (66,730 kg), gutted weight; 153,000 lb (69,400 kg), round weight.

(ii) For the 2014 fishing year—148,558 lb (67,385 kg), gutted weight; 154,500 lb (70,080 kg), round weight.

(iii) For the 2015 and subsequent fishing years—157,692 lb (71,528 kg), gutted weight; 164,000 lb (74,389 kg), round weight.

* * * * *

■ 4. In § 622.191, paragraph (a)(6) is revised to read as follows:

§ 622.191 Commercial trip limits.

* * * * *

(a) * * *

(6) *Vermilion snapper.* (i) Until 75 percent of either quota specified in § 622.190(a)(4)(i) or (ii) is reached or projected to be reached, 1,000 lb (454 kg), gutted weight; 1,110 lb (503 kg), round weight.

(ii) After 75 percent of either quota specified in § 622.190(a)(4)(i) or (ii) is reached or projected to be reached, 500 lb (227 kg), gutted weight; 555 lb (252 kg), round weight. The Assistant Administrator, by filing a notification with the Office of the Federal Register, will effect a trip limit change specified in this paragraph, (a)(6)(ii), when the applicable conditions have been reached.

(iii) See § 622.190(c)(1) for the limitations regarding vermilion snapper after either quota is reached.

* * * * *

■ 5. In § 622.193, paragraphs (f) and (v) are revised to read as follows:

§ 622.193 Annual catch limits (ACLs), annual catch targets (ACTs), and accountability measures (AMs).

* * * * *

(f) *Vermilion snapper*—(1) *Commercial sector.* If commercial landings, as estimated by the SRD, reach or are projected to reach the applicable commercial ACL (commercial quota) specified in § 622.190(a)(4)(i) or (ii), the AA will file a notification with the Office of the Federal Register to close the commercial sector for that portion of the fishing year applicable to the respective quota.

(2) *Recreational sector.* (i) If recreational landings, as estimated by the SRD, reach or are projected to reach the applicable recreational ACL specified in paragraph (f)(2)(iv) of this section and vermilion snapper are overfished, based on the most recent Status of U.S. Fisheries Report to Congress, the AA will file a notification with the Office of the Federal Register to close the recreational sector for vermilion snapper for the remainder of the fishing year. On and after the effective date of such notification, the bag and possession limit of vermilion snapper in or from the South Atlantic EEZ is zero. This bag and possession limit also applies in the South Atlantic on board a vessel for which a valid Federal commercial or charter vessel/headboat permit for South Atlantic snapper-grouper has been issued, without regard to where such species were harvested, *i.e.,* in state or Federal waters.

(ii) Without regard to overfished status, if vermilion snapper recreational landings exceed the applicable recreational ACL, the AA will file a notification with the Office of the Federal Register, at or near the beginning of the following fishing year, to reduce the ACL for that fishing year by the amount of the overage.

(iii) Recreational landings will be evaluated relative to the ACL based on a moving multi-year average of landings, as described in the FMP.

(iv) The recreational ACL for vermilion snapper is 395,532 lb (179,410 kg), gutted weight, 439,040 lb (199,145 kg), round weight, for 2013; 378,234 lb (171,564 kg), gutted weight, 419,840 lb (190,436 kg), round weight, for 2014; 371,604 lb (168,557 kg), gutted weight, 412,480 lb (187,098 kg), round weight, for 2015; and 365,838 lb (165,941 kg), gutted weight, 406,080 lb (184,195 kg), round weight, for 2016 and subsequent fishing years.

* * * * *

(v) *Red porgy*—(1) *Commercial sector.* (i) If commercial landings for red porgy, as estimated by the SRD, reach or are projected to reach the applicable commercial ACL (commercial quota) specified in § 622.190(a)(6), the AA will

file a notification with the Office of the Federal Register to close the commercial sector for the remainder of the fishing year.

(ii) If commercial landings exceed the applicable commercial ACL, and red porgy are overfished, based on the most recent Status of U.S. Fisheries Report to Congress, the AA will file a notification with the Office of the Federal Register, at or near the beginning of the fishing year to reduce the ACL for that following year by the amount of the overage in the prior fishing year.

(2) *Recreational sector.* (i) If recreational landings for red porgy, as estimated by the SRD, exceed the applicable recreational ACL specified in paragraph (v)(2)(ii) of this section then during the following fishing year, recreational landings will be monitored for a persistence in increased landings and, if necessary, the AA will file a notification with the Office of the Federal Register, to reduce the length of the following recreational fishing season by the amount necessary to ensure recreational landings do not exceed the recreational ACL in the following fishing year. However, the length of the recreational fishing season will not be reduced during the following fishing year if recreational landings do not exceed the applicable ACL or if the RA determines, using the best scientific information available, that a reduction in the length of the following fishing season is unnecessary.

(ii) The recreational ACL for red porgy is 147,115 lb (66,730 kg), gutted weight, 153,000 lb (69,400 kg), round weight, for 2013; 148,558 lb (67,385 kg), gutted weight, 154,500 lb (70,080 kg), round weight, for 2014; 157,692 lb (71,528 kg), gutted weight, 164,000 lb (74,389 kg), round weight, for 2015 and subsequent fishing years.

* * * * *

[FR Doc. 2013–10804 Filed 5–7–13; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 78, No. 89

Wednesday, May 8, 2013

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

Rural Business-Cooperative Service

Amendment to Notice of Funding Availability for the Rural Energy for America Program

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice.

SUMMARY: The Rural Business-Cooperative Service (Agency) published a notice in the **Federal Register** of March 29, 2013, (78 FR Doc. 2013–07275) announcing the acceptance of applications for funds available under the Rural Energy for America Program (REAP) for Fiscal Year 2013. The Consolidated and Further Continuing Appropriations Act, 2013 (Pub. L. 113–6), provides additional funding for REAP. To provide the public additional opportunity to apply for these additional funds, this Notice extends the application period from April 30, 2013, to May 31, 2013, for renewable energy systems and energy efficiency improvement projects grants and grant and loan combination applications and for renewable energy system feasibility study applications. The Agency is also adding a provision to ensure consistency with the intent of 2 CFR 25.205. A separate notice will be published to amend the funding available under REAP.

FOR FURTHER INFORMATION CONTACT: For information about this Notice, please contact Mr. Kelley Oehler, Branch Chief, USDA Rural Development, Energy Division, 1400 Independence Avenue SW., Washington, DC 20250. Telephone: (202) 720–6819. Email: *kelley.oehler@wdc.usda.gov*.

SUPPLEMENTARY INFORMATION: The Agency is amending the **DATES** section in the Notice of Funding Availability for the Rural Energy for America Program, which was published on March 29, 2013 (78 FR Doc. 2013–07275). To provide the public additional time to submit applications as the result of additional funding being made available to the Agency, the Agency is extending the application deadline for three sets of applications: (1) Renewable energy system (RES) and energy efficiency improvement (EEI) grants, (2) RES and EEI grant and loan combinations and (3) RES feasibility study grants. For this set of applications, the deadline is being extended from April 30, 2013, to May 31, 2013. Note that the application deadline for RES and EEI guaranteed loan only applications is not being modified. The Agency is adding a provision to conform with the intent of 2 CFR 25.205, which allows the Agency to determine an applicant is not eligible for an award if the System for Award Management and Dun and Bradstreet Data Universal Numbering System requirements are not met. No other changes are being made to the March 29, 2013, Notice at this time.

Summary of Changes

1. In the third column on page 19183, the second paragraph under the **DATES** section is revised to read as follows:

For renewable energy system and energy efficiency improvement grant applications and combination grant and guaranteed loan applications, no later than 4:30 p.m. local time May 31, 2013.

2. In the third column on page 19183, the fourth paragraph under the **DATES** section is revised to read as follows:

For renewable energy system feasibility study applications, no later than 4:30 p.m. local time May 31, 2013.

3. In the first column on page 19187, subparagraph (d) is being added after subparagraph E. (4)(c) and before subparagraph (5), to read as follows:

(d) At the time the Agency is ready to make an award, if the applicant has not complied with subparagraph E. (4)(a) through (c) of this section, the Agency may determine the applicant is not eligible to receive the award.

Nondiscrimination Statement

USDA prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

To file a complaint of discrimination, write to: USDA, Assistant Secretary for Civil Rights, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Stop 9410, Washington, DC 20250–9410 or call toll-free at (866) 632–9992 (English) or (800) 877–8339 (TDD) or (866) 377–8642 (English Federal-relay) or (800) 845–6136 (Spanish Federal-relay). USDA is an equal opportunity provider and employer.

Dated: April 29, 2013.

Lillian E. Salerno,

Acting Administrator, Rural Business-Cooperative Service.

[FR Doc. 2013–10941 Filed 5–7–13; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Oglethorpe Power Corporation: Proposed Biomass Power Plant

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of Availability of a Record of Decision.

SUMMARY: The Rural Utilities Service (RUS) has issued a Record of Decision (ROD) for the Environmental Impact Statement (EIS) related to providing financial assistance to the Oglethorpe Power Corporation (Oglethorpe) for the construction of a 100 megawatt (MW) biomass plant and related facilities (Proposal) in Warren County, Georgia. The Administrator of RUS has signed the ROD, which was effective upon signing. The EIS was prepared pursuant to the National Environmental Policy Act (NEPA) (U.S.C. 4231 et seq.) and in accordance with the Council on Environmental Quality's (CEQ) regulations for implementing the procedural provisions of NEPA (40 CFR Parts 1500–1508) and RUS' Environmental Policies and Procedures (7 CFR part 1794). As the lead federal agency, and as part of its broad environmental review process, RUS must take into account the effect of the Proposal on historic properties in

accordance with Section 106 of the National Historic Preservation Act (16 U.S.C. 470f) and its implementing regulation ''Protection of Historic Properties'' (36 CFR Part 800). Pursuant to 36 CFR 800.2(d)(3), RUS used its procedures for public involvement under NEPA, in part, to meet its responsibilities to solicit and consider the views of the public and other interested parties during the Section 106 review process. Accordingly, comments submitted in the EIS process also informed RUS's decision making in the Section 106 review process. The purpose of the Proposal is to provide a reliable, long-term supply of renewable and sustainable energy at a reasonable cost to meet part of the electric energy needs of Oglethorpe's members.

The Final EIS evaluated the potential environmental impacts of and alternatives to the Project proposed by Oglethorpe for RUS financing to construct the 100 megawatt (MW) biomass plant and related facilities (Proposal) in Warren County, Georgia

ADDRESSES: To obtain copies of the ROD, or for further information, contact: Ms. Stephanie Strength, Environmental Protection Specialist, USDA, Rural Utilities Service, 1400 Independence Avenue SW., Stop 1571, Room 2244–S, Washington, DC 20250–1571, telephone: (970) 403–3559, fax: (202) 690–0649, or email: *stephanie.strength@wdc.usda.gov.* The ROD is available online at: *http://www.rurdev.usda.gov/UWP-OglethorpePower.html* and at the: Warren County Public Library, 10 Warren Street, Warrenton, Georgia 30828, Phone (706) 465- 2656.

SUPPLEMENTARY INFORMATION: Oglethorpe proposes to own, operate, and maintain the Proposal in Warren County, Georgia. Three alternatives are evaluated in detail in the Final EIS; the no action alternative, and the proposed action at two different locations: Warren County (the Proposal) and Appling County (the Alternate). These alternatives were evaluated in terms of cost-effectiveness, technical feasibility, and environmental factors (e.g., soils, topography and geology, water resources, air quality, biological resources, the acoustic environment, recreation, cultural and historic resources, visual resources, transportation, farmland, land use, human health and safety, the socioeconomic environment, environmental justice, and cumulative effects).

The Proposal would be constructed on an approximately 343-acre site located three-fourths mile east of the city limit of Warrenton, Georgia. The tallest structure would be the stack, with a maximum estimated height of approximately 220 feet.

A Notice of Availability (NOA) of the Draft EIS was published in the **Federal Register** at 76 FR 20624, on April 13, 2011, and in newspapers of general circulation within the Proposal's area of environmental impact. Public hearings on the Draft EIS were held in the project area on May 5, 2011, and public comments were accepted through May 31, 2011. All comments on the Draft EIS have been entered into the administrative record, responses are included in the Final EIS, and the Final EIS was modified as appropriate. RUS published its NOA of the Final EIS for the proposed Project in the **Federal Register** on December 15, 2011 at 76 FR 77963. The U.S. Environmental Protection Agency acknowledged receipt of the Final EIS on December 9, 2011, from RUS. The 30-day waiting period ended on January 9, 2012. Fifteen comments were received that did not result in the need for changes or further comment in RUS's ROD.

RUS carefully studied public health and safety, environmental impacts, and engineering aspects of the Project. Based on an evaluation of the information and impact analyses presented in the EIS, RUS finds that the evaluation of reasonable alternatives is consistent with NEPA and RUS Environmental Policies and Procedures. Details regarding RUS's regulatory authority, rationale for the decision, and compliance with applicable regulations are included in the ROD. Because the proposed Project may involve action in floodplains or wetlands, this Notice also serves as a final notice of action in floodplains and wetlands (in accordance with Executive Orders 11988 and 11990).

This ROD is not a decision on Ogelthorpe's loan application and therefore not an approval of the expenditure of federal funds. This notice of the ROD concludes RUS's environmental review process in accordance with NEPA and RUS's Environmental Policies and Procedures (7 CFR part 1794). The ultimate decision as to loan approval depends upon the conclusion of this environmental review process plus financial and engineering analyses. Issuance of the ROD will allow these reviews to proceed.

Dated: March 15, 2013.

John Charles Padalino,

Acting Administrator, Rural Utilities Service.

[FR Doc. 2013–10861 Filed 5–7–13; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–904]

Certain Activated Carbon From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2011–2012

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: In response to requests from interested parties, the Department of Commerce (''Department'') is conducting the administrative review of the antidumping duty order on certain activated carbon from the People's Republic of China (''PRC'') for the period of review (''POR'') April 1, 2011, through March 31, 2012. The Department has preliminarily determined that sales have been made below normal value (''NV''). Additionally, the Department has preliminarily determined not to revoke the order, in part, with respect to Jacobi Carbons AB (''Jacobi'').

DATES: *Effective Date:* May 8, 2013.

FOR FURTHER INFORMATION CONTACT: Bob Palmer, Emeka Chukwudebe, and Ricardo Martinez Rivera, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–9068, (202) 482–0219, and (202) 482–4532, respectively.

SUPPLEMENTARY INFORMATION:

Scope of the Order

The merchandise subject to the order is certain activated carbon.[1] The products are currently classifiable under the Harmonized Tariff Schedule of the United States (''HTSUS'') subheading 3802.10.00. Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of the order remains dispositive.[2]

[1] *See* ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Certain Activated Carbon from the People's Republic of China,'' (''Preliminary Decision Memorandum'') from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Import Administration, issued concurrently with this notice, for a complete description of the Scope of the Order.

[2] *See Notice of Antidumping Duty Order: Certain Activated Carbon from the People's Republic of China,* 72 FR 20988 (April 27, 2007) (''*Order*'').

Methodology

The Department has conducted this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (''the Act''). Constructed export prices and export prices have been calculated in accordance with section 772 of the Act. Because the PRC is a non-market economy (''NME'') within the meaning of section 771(18) of the Act, NV has been calculated in accordance with section 773(c) of the Act. Specifically, the mandatory respondent's factors of production (''FOPs'') (with the exception of steam) have been valued with prices from a surrogate country which is economically comparable to the PRC and is a significant producer of comparable merchandise.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum dated concurrently with these results and hereby adopted by this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Import Administration's 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 (''CRU''), room 7046 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the internet at *http://www.trade.gov/ia/*. The signed Preliminary Decision Memorandum and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Intent Not To Revoke Order In Part

We preliminarily determine [3] that we should not revoke the *Order* in part with respect to Jacobi under section 751 of the Act, because we find that Jacobi has not satisfied the requirements of 19 CFR 351.222(b).[4]

Verification

As provided in sections 782(i)(3)(A)–(B) of the Act, we intend to verify the information upon which we will rely in determining our final results of review with respect to Jacobi.

Preliminary Results of the Review

The Department has determined that the following preliminary dumping margins exist:

Exporter	Margin (Dollars Per Kilogram) [5]
Jacobi Group [6]	0.56
Ningxia Huahui Activated Carbon Co., Ltd	0.29
Calgon Carbon (Tianjin) Co., Ltd	0.43
Datong Juqiang Activated Carbon Co., Ltd	0.43
Datong Municipal Yunguang Activated Carbon Co., Ltd	0.43
Jilin Bright Future Chemicals Company, Ltd	0.43
Ningxia Guanghua Cherishmet Activated Carbon Co., Ltd.[7]	0.43
Ningxia Mineral and Chemical Limited	0.43
Shanxi DMD Corporation	0.43
Shanxi Sincere Industrial Co., Ltd	0.43
Shanxi Industry Technology Trading Co., Ltd	0.43
Sinoacarbon International Trading Co., Ltd	0.43
Tancarb Activated Carbon Co., Ltd	0.43
Tangshan Solid Carbon Co., Ltd	0.43
Tianjin Maijin Industries Co., Ltd	0.43
PRC-Wide Rate [8]	2.42

Disclosure and Public Comment

The Department intends to disclose calculations performed for these preliminary results to the parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

In accordance with 19 CFR 351.301(c)(3)(ii), for the final results of this administrative review, interested parties may submit publicly available information to value FOPs within 20 days after the date of publication of these preliminary results. Interested parties must provide the Department with supporting documentation for the publicly available information to value each FOP. Additionally, in accordance with 19 CFR 351.301(c)(1), for the final results of this administrative review, interested parties may submit factual information to rebut, clarify, or correct factual information submitted by an interested party less than ten days before, on, or after, the applicable deadline for submission of such factual information. However, the Department notes that 19 CFR 351.301(c)(1) permits new information only insofar as it rebuts, clarifies, or corrects information recently placed on the record. The Department generally cannot accept the submission of additional, previously absent from the record alternative surrogate value information pursuant to 19 CFR 351.301(c)(1).[9] Additionally, for each piece of factual information submitted with surrogate value rebuttal comments, the interested party must provide a written explanation of what information is already on the record of the ongoing proceeding which the factual information is rebutting, clarifying, or correcting.

Because, as noted above, the Department intends to verify the

[3] *See* Preliminary Decision Memorandum, at 5.

[4] The Department recently modified the section of its regulations concerning the revocation of antidumping and countervailing duty orders in whole or in part, but that modification does not apply to this administrative review as it was initiated before June 20, 2012. *See Modification to Regulation Concerning the Revocation of Antidumping and Countervailing Duty Orders,* 77 FR 29875 (May 21, 2012). Reference to 19 CFR 351.222(b) thus refers to the Department's regulations prior to the modification.

[5] In the second administrative review of this order, the Department determined that it would calculate per-unit assessment and cash deposit rates for all future reviews. *See Certain Activated Carbon From the People's Republic of China: Final Results and Partial Rescission of Second Antidumping Duty Administrative Review,* 75 FR 70208, 70211 (November 17, 2010).

[6] In *the third administrative review,* the Department found Jacobi, Tianjin Jacobi International Trading Co. Ltd., and Jacobi Carbons Industry (Tianjin) (collectively, ''Jacobi Group'') are a single entity and, because there were no changes to the facts which supported that decision, we continued to find these companies part of a single entity in *the fourth administrative review.* Because there have been no changes to the facts which supported that decision in the present review, we will assign this rate to the companies in the single entity. *See* Preliminary Decision Memorandum, at 16, at ''Affiliation and Collapsing''; *see also Certain Activated Carbon From the People's Republic of China: Final Results and Partial Rescission of Third Antidumping Duty Administrative Review,* 76 FR 67142 (October 31, 2011); *Certain Activated Carbon From the People's Republic of China; 2010–2011; Final Results of Antidumping Duty Administrative Review,* 77 FR 67337, 67339 at footnote 22 (November 9, 2012) (''*AR4 Carbon*'').

[7] In *the first administrative review,* the Department found Beijing Pacific Activated Carbon Products Co., Ltd., Ningxia Guanghua Cherishmet Activated Carbon Co., Ltd., and Ningxia Guanghua Activated Carbon Co., Ltd. are a single entity and, because there were no changes to the facts which supported that decision, we continued to find these companies to be part of a single entity in *AR4 Carbon.* Because there have been no changes to the facts which supported that decision in the present review, we will assign this rate to the companies in the single entity. *See Certain Activated Carbon From the People's Republic of China: Notice of Preliminary Results of the Antidumping Duty Administrative Review and Extension of Time Limits for the Final Results,* 74 FR 21317 (May 7, 2009), unchanged in *First Administrative Review of Certain Activated Carbon from the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 74 FR 57995 (November 10, 2009); *AR4 Carbon,* 77 FR at 67339 at footnote 23.

[8] The PRC-Wide entity includes Datong Locomotive Coal & Chemicals Co., Ltd., Ningxia Lingzhou Foreign Trade Co., Ltd. and Shanxi Qixian Foreign Trade Corporation.

[9] *See Glycine From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Rescission, in Part,* 72 FR 58809 (October 17, 2007), and accompanying Issues and Decision Memorandum at Comment 2.

information upon which we will rely in making our final determination, the Department will establish the briefing schedule at a later time, and will notify parties of the schedule in accordance with 19 CFR 351.309. Parties who submit case briefs or rebuttal briefs in this proceeding are requested to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[10]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, within 30 days of the date of publication of this notice. Requests should contain: (1) The party's name, address and telephone number; (2) The number of participants; and (3) A list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs.

Assessment Rates

Upon issuance of the final results, the Department will determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries covered by this review.[11] The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of this review. For any individually examined respondent whose weighted average dumping margin is above *de minimis* (*i.e.,* is 0.50 percent or more) in the final results of this review, the Department will calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales and the total entered value of sales, in accordance with 19 CFR 351.212(b)(1).[12] We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate calculated in the final results of this review is above *de minimis.* Where either the respondent's weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For those companies not assigned a separate rate from a prior segment of the proceeding, the Department has stated that they are not separate from the PRC-wide entity and that the administrative review will continue for these companies.[13]

The Department recently announced a refinement to its assessment practice in NME cases. Pursuant to this refinement in practice, for entries that were not reported in the U.S. sales databases submitted by companies individually examined during this review, the Department will instruct CBP to liquidate such entries at the PRC-wide rate. Additionally, if the Department determines that an exporter had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the PRC-wide rate.[14]

The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by sections 751(a)(2)(C) of the Act: (1) For each specific company listed above, the cash deposit rate will be that established in the final results of this review (except, if the rate is zero or *de minimis,* then zero cash deposit will be required); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the PRC-wide entity; and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter that supplied that non-PRC exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This determination is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: May 2, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

1. Respondent Selection
2. Questionnaires
3. Scope of the Order
4. Request for Revocation, In Part
5. Withdrawal of Request for Review
6. Non-Market Economy Country
7. Separate Rates
8. Separate Rate Calculation
9. PRC—Wide Entity
10. Surrogate Country and Surrogate Value Data
11. Surrogate Country
12. Economic Comparability
13. Significant Producers of Comparable Merchandise
14. Data Availability
15. Affiliations and Collapsing
16. Facts Available for NV
17. Date of Sale
18. Comparisons to Normal Value
19. U.S. Price
20. Normal Value
21. Use of Facts Available and Adverse Facts Available for EP/CEP
22. Currency Conversion

[FR Doc. 2013–10943 Filed 5–7–13; 8:45 am]

BILLING CODE 3510–DS–P

[10] *See* 19 CFR 351.309(c) and (d).

[11] *See* 19 CFR 351.212(b).

[12] In these preliminary results, the Department applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012).

[13] *See* footnote 6.

[14] For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

DEPARTMENT OF COMMERCE

International Trade Administration

Advisory Committee on Supply Chain Competitiveness: Notice of Public Meeting

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: This notice sets forth the schedule and proposed topics of discussion for a public meeting of the

Advisory Committee on Supply Chain Competitiveness (Committee).

DATES: The meeting will be held on June 4, 2013, from 10:00 a.m. to 2:00 p.m., Eastern Standard Time (EST).

ADDRESSES: The meeting will be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Room 6029, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Richard Boll, Office of Service Industries, International Trade Administration. (Phone: (202) 482–1135 or Email: *richard.boll@trade.gov*).

SUPPLEMENTARY INFORMATION:

Background

The Committee was established under the discretionary authority of the Secretary of Commerce and in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2). It provides advice to the Secretary of Commerce on the necessary elements of a comprehensive, holistic national freight infrastructure and a national freight policy designed to support U.S. export and growth competitiveness, foster national economic competitiveness, and improve U.S. supply chain competitiveness in the domestic and global economy. For more information about the Committee visit: *http://ita.doc.gov/td/sif/DSCT/ACSCC/*.

Matters To Be Considered: Committee members are expected to continue to discuss the major competitiveness-related topics raised at the previous Committee meetings, including trade and competitiveness; freight movement and policy; information technology and data requirements; regulatory issues; and finance and infrastructure. The Committee's subcommittees will report on the status of their work regarding these topics. The agenda may change to accommodate Committee business. The Office of Service Industries will post the final detailed agenda on its Web site, *http://ita.doc.gov/td/sif/DSCT/ACSCC/*, at least one week prior to the meeting. The meeting will be open to the public and press on a first-come, first-served basis. Space is limited. The public meeting is physically accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Mr. Richard Boll, at (202) 482–1135 or *richard.boll@trade.gov* five (5) business days before the meeting.

Interested parties are invited to submit written comments to the Committee at any time before and after the meeting. Parties wishing to submit written comments for consideration by the Committee in advance of this meeting must send them to the Office of Service Industries (OSI), 1401 Constitution Ave. NW., Room 11014, Washington, DC 20230, or email to *supplychain@trade.gov*.

For consideration during the meeting, and to ensure transmission to the Committee prior to the meeting, comments must be received no later than 5:00 p.m. EST on May 25, 2013. Comments received after May 25, 2013, will be distributed to the Committee, but may not be considered at the meeting. The minutes of the meeting will be posted on the Committee Web site within 60 days of the meeting.

Dated: April 30, 2013.

David Long,

Director, Office of Service Industries.

[FR Doc. 2013–10869 Filed 5–7–13; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC645

Taking of Threatened or Endangered Marine Mammals Incidental to Commercial Fishing Operations; Issuance of Permit

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

ACTION: Notice; request for comments.

SUMMARY: NMFS plans to issue a permit for a period of three years to authorize the incidental, but not intentional, taking of three stocks of marine mammals listed as threatened or endangered under the Endangered Species Act (ESA) by the California (CA) thresher shark/swordfish drift gillnet (DGN) fishery (≥14 inch mesh) and the Washington/Oregon/California (WA/OR/CA) sablefish pot fishery. In accordance with the Marine Mammal Protection Act (MMPA), NMFS has made a preliminary determination that incidental taking from commercial fishing will have a negligible impact on the endangered fin whale, CA/OR/WA stock; humpback whale, CA/OR/WA stock; and sperm whale, CA/OR/WA stock. Recovery plans have been completed for these endangered species. This authorization is based on a determination that this incidental take will have a negligible impact on the affected marine mammal stocks. NMFS must issue this permit provided that we can make the determinations that: the incidental take will have a negligible impact on the affected marine mammal stocks; a recovery plan for all affected stocks of threatened or endangered marine mammals has been developed or is being developed; and as required by the MMPA, a take reduction plan and monitoring program have been implemented and vessels in the CA thresher shark/swordfish DGN fishery (≥14 inch mesh) and WA/OR/CA sablefish pot fishery are registered. NMFS solicits public comments on the draft negligible impact determination and on the proposal to issue a permit to these fisheries for the taking of affected threatened or endangered stocks of marine mammals.

DATES: Comments must be received by June 7, 2013.

ADDRESSES: A draft of the negligible impact determination is available on the Internet at the following addresses: *http://swr.nmfs.noaa.gov/.* Recovery plans for these species are available on the Internet at the following address: *http://www.nmfs.noaa.gov/pr/recovery/plans.htm#mammals.*

You may submit comments, identified by NOAA–NMFS–2013–0073, by any of the following methods:

E*lectronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2013-0073,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

Mail: Send comments or requests for copies of reports to: Chris Yates, Assistant Regional Administrator, Protected Resources Division, Southwest Region, NMFS, 501 W Ocean Blvd., Suite 4200, Long Beach, CA 90802 Comments may also be faxed to (562) 980–4027.

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

FOR FURTHER INFORMATION CONTACT: Monica DeAngelis, NMFS Southwest

Region, (562) 980–3232, or Shannon Bettridge, NMFS Office of Protected Resources, (301) 427–8402.

SUPPLEMENTARY INFORMATION:

Background

Section 101(a)(5)(E) of the Marine Mammal Protection Act (MMPA), 16 U.S.C. 1361 *et seq.,* states that NOAA's National Marine Fisheries Service (NMFS), as delegated by the Secretary of Commerce, shall for a period of up to three years allow the incidental taking of marine mammal species listed under the Endangered Species Act (ESA), 16 U.S.C. 1531 *et seq.,* by persons using vessels of the United States and those vessels which have valid fishing permits issued by the Secretary in accordance with section 204(b) of the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1824(b), while engaging in commercial fishing operations, if NMFS makes certain determinations. NMFS must first determine, after notice and opportunity for public comment, that: (1) Incidental mortality and serious injury will have a negligible impact on the affected species or stock; (2) a recovery plan has been developed or is being developed for such species or stock under the ESA; and (3) where required under section 118 of the MMPA, a monitoring program has been established, vessels engaged in such fisheries are registered in accordance with section 118 of the MMPA, and a take reduction plan has been developed or is being developed for such species or stock.

NMFS is considering the issuance of a permit under MMPA section 101(a)(5)(E) to vessels registered in the CA thresher shark/swordfish DGN fishery (≥14 inch mesh) and the WA/OR/CA sablefish pot fishery (both Federal Category II fisheries) to incidentally take three stocks of threatened or endangered marine mammals: the CA/OR/WA stock of fin whales (*Balaenoptera physalus*), the CA/OR/WA stock of humpback whales (*Megaptera novaeangliae*), and the CA/OR/WA stock of sperm whales (*Physeter macrocephalus*). A history of MMPA section 101(a)(5)(E) permits related to these stocks was included in previous notices for other permits to take threatened or endangered marine mammals incidental to commercial fishing (*e.g.* 72 FR 60814; October 26, 2007). The data for considering these authorizations were reviewed coincident with the preparation of the 2012 MMPA List of Fisheries (LOF or List) (76 FR 73912; November 29, 2011), the 2011 marine mammal stock assessment reports (SARs) (Carretta *et al.* 2012; Allen and Angliss 2011), the Fishery Management Plan (FMP) for U.S. West Coast Fisheries for Highly Migratory Species (HMS), recovery plans for these species (available on the Internet at the following address: *http://www.nmfs.noaa.gov/pr/recovery/plans.htm#mammals),* and other relevant sources.

Based on observer data and marine mammal reporting forms, the California thresher shark/swordfish drift gillnet fishery (≥14 in mesh) and the Washington/Oregon/California sablefish pot fishery are the Category II fisheries that operate in the ranges of affected stocks, namely the CA/OR/WA stocks of fin, sperm whales, and humpback whales, and are currently considered for authorization. A detailed description of these fisheries can be found below. All other Category II fisheries that interact with the marine mammal stocks observed off the coasts of Washington, Oregon, and California are State-managed and are not considered for authorization under this permit. NMFS calculated the total human-related serious injury and mortality to make a negligible impact determination for this proposed authorization and included all human sources, such as commercial fisheries and ship strikes. There are no fisheries classified as Category I fisheries that interact with the marine mammal stocks observed off the coasts of Washington, Oregon, or California. Participants in Category III fisheries are not required to obtain incidental take permits under MMPA section 101(a)(5)(E), but are required to report injuries or mortality of marine mammals incidental to their operations.

Basis for Determining Negligible Impact

Prior to issuing a permit to take ESA-listed marine mammals incidental to commercial fishing, NMFS must determine if mortality and serious injury incidental to commercial fisheries will have a negligible impact on the affected species or stocks of marine mammals. NMFS satisfied this requirement through completion of a draft negligible impact determination (NID). NMFS clarifies that incidental mortality and serious injury include only direct mortality and serious injury, such as from entanglement or hooking in fishing gear. Indirect effects, such as the effects of removing prey from habitat, are not included in this analysis. A biological opinion prepared under ESA section 7 considers direct and indirect effects of Federal actions and, thus, contains a broader scope of analysis than is required by MMPA section 101(a)(5)(E).

Section 101(a)(5)(E) of the MMPA requires the authorization of the incidental taking of individuals from marine mammal stocks listed as threatened or endangered under the ESA in the course of commercial fishing operations if NMFS determines, among other things, that incidental mortality and serious injury will have a negligible impact on the affected species or stock. Although the MMPA does not define ''negligible impact,'' NMFS has issued regulations providing a qualitative definition of ''negligible impact,'' as defined in 50 CFR 216.103 and, through scientific analysis, peer review, and public notice, developed a quantitative approach and as it applies here is, ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.'' The development of the approach and process was outlined in detail in the current draft NID made available through this notice and was included in previous notices for other permits to take threatened or endangered marine mammals incidental to commercial fishing (e.g. 72 FR 60814; October 26, 2007; for the CA/OR/WA stock of fin, humpback, and sperm whales).

Criteria for Determining Negligible Impact

In 1999 NMFS adopted criteria for making negligible impact determinations for MMPA 101(a)(5)(E) permits (64 FR 28800; May 27, 1999). In applying the 1999 criteria to determine whether mortality and serious injury incidental to commercial fisheries will have a negligible impact on a listed marine mammal stock, Criterion 1 (total human-related serious injury and mortality are less than 0.1 potential biological removal level (PBR)) is the starting point for analysis. If this criterion is satisfied (*i.e.,* total human-related serious injuries and mortality are less than 0.1 PBR), the analysis would be concluded, and the impact would be determined to be negligible. The remaining criteria describe alternatives under certain conditions, such as fishery mortality below the negligible threshold but other human-caused mortality above the threshold or fishery and other human-caused mortality between the negligible threshold and PBR for a stock that is increasing or stable. If Criterion 1 is not satisfied, NMFS may use one of the other criteria as appropriate. Criterion 2 is satisfied if the total human-related serious injury and mortality are greater than PBR, and fisheries-related mortality is less than

0.1 PBR. If Criterion 2 is satisfied, individual fisheries may be permitted if management measures are being taken to address non-fisheries-related serious injuries and mortality. Criterion 3 is satisfied if total fisheries-related serious injury and mortality are greater than 0.1 PBR and less than PBR and the population is stable or increasing, fisheries may be permitted subject to individual review and certainty of data. Criterion 4 stipulates that if the population abundance of a stock is declining, the threshold level of 0.1 PBR will continue to be used. Criterion 5 states that if total fisheries-related serious injuries and mortalities are greater than PBR, permits may not be issued.

We used two time frames for this analysis. The first time frame for the data used in this analysis is from 1998 (the first full year post-Take Reduction Plan implementation (October 30, 1997)), through December 31, 2011. This 14-year time frame was chosen initially because after the Pacific Offshore Cetacean Take Reduction Plan (POCTRP) was implemented, regulations required skippers to use at least 36' extenders and pingers in the CA thresher shark/swordfish DGN fishery (≥14 inch mesh), which is considered to have reduced the incidental take of many marine mammal species, particularly cetaceans (Carretta and Barlow 2011). This time frame also provided a comprehensive look at all of the fisheries, including the WA/OR/CA sablefish pot fishery, given changes in oceanographic conditions, fishing practices, and reporting and stranding records. The 2001 time/area closure of the CA thresher shark/swordfish DGN fishery (≥14 inch mesh) off central and northern California/southern Oregon is also encompassed in this time frame. The second time frame for the data used in this analysis includes the most recent five-year period (January 1, 2007 through December 31, 2011). A five-year time frame provides enough data to adequately capture year-to-year variations in take levels, while reflecting current environmental and fishing conditions as they may change over time. Additionally, because the permit issued under MMPA section 101(a)(5)(E) is for a three-year period, the most up-to-date data available for complete years is used (*i.e.,* 2007–2011).

A conservative, or precautionary, approach is taken in these analyses for evaluating the negligible impact of fisheries and other sources of injury or mortality, such as ship strikes, on these stocks, so in certain cases, the maximum number was used for the calculations. For example, if a ship strike occurred, but serious injury or mortality was not observed on scene or confirmed by necropsy of the stranded animal, and if further review of reports and other sources then confirmed serious injury/mortality, it was assumed for purposes of this analysis, that serious injury/mortality occurred, and was included in the total number used in the calculation. Furthermore, in using two time frames for the negligible impact analyses (1998–2011 and 2007–2011), we took a precautionary approach by ensuring that a negligible impact determination could be made for both time frames considered.

Negligible Impact Determinations

In considering the appropriate criteria for determining whether commercial fisheries off the U.S. west coast are having a negligible impact on the CA/OR/WA stocks of fin whales, humpback whales, and sperm whales, a summary of the negligible impact determinations follows.

Criterion 1 Analysis

Criterion 1 would be satisfied if the total human-related serious injury and mortality are less than PBR.

- The 14-year (1998–2011) annual average serious injury and mortality to the CA/OR/WA stock of fin whales from all human-caused sources is 1.43, or 8.93% of the PBR. The 5-year (2007–2011) annual average annual average serious injury and mortality from all human-caused sources is 2.2 or 13.8% of the PBR. The total annual human-related serious injury and mortality for this stock of fin whales is not less than 0.1 PBR for both time frames considered.
- The 14-year (1998–2011) average annual serious injury and mortality to the CA/OR/WA stock of humpback whales from all human sources is 4.31, or 38.2% of the PBR. The 5-year (2007–2011) average annual human-caused mortality or serious injury is 7.2 or 63.7% of the PBR. The total annual human-related serious injury and mortality for this stock of humpback whales is not less than 0.1 PBR for both time frames considered.
- The 14-year (1998–2011) average annual serious injury and mortality to the CA/OR/WA stock of sperm whales from all human sources is 0.79, or 52.6% of the PBR. The 5-year (2007–2011) average annual human-caused mortality or serious injury is 1.4 or 93.3% of the PBR. The total annual human-related serious injury and mortality for this stock of sperm whales is not less than 0.1 PBR for both time frames considered.

Criterion 1 was not satisfied because the total annual human-related serious injury for fin, humpback, and sperm whales are not less than 0.1 PBR of each stock for both time frames considered. As a result, the other criteria must be examined for the CA/OR/WA fin, humpback, and sperm whale stocks.

Criterion 2 Analysis

Criterion 2 would be satisfied if the total human-related serious injury and mortality are greater than PBR, and fisheries-related mortality is less than 0.1 PBR. This criterion was not satisfied because total human-related serious injury and mortality (detailed above) is less than PBR, and total fisheries-related mortality (detailed below) is greater than 0.1 PBR for each stock (both time frames analyzed).

Criterion 3 Analysis

Unlike Criteria 1 and 2, which examine total human-caused serious injury and mortality relative to PBR, Criterion 3 compares total fisheries-related serious injury and mortality to PBR. Criterion 3 would be satisfied if the total fisheries-related serious injury and mortality (including state and federal fisheries) is greater than 0.1 PBR and less than 1.0 PBR for each stock, for each time frame considered and the populations of these stocks are considered to be stable or increasing.

The total fishery-related mortality and serious injury is a small portion of the CA/OR/WA fin whale stock's PBR (of 16): 3.8% of PBR for the 5-year average from 2007–2011, and 1.8% of PBR for the 14-year average from 1998–2011. The CA/OR/WA fin whale stock's PBR is calculated using a recovery factor of 0.3, and a minimum population size of 2,624; this population is growing at a rate of about 3%/year (a little less than the default maximum net growth rate for cetaceans of 4%). The likelihood that fin whales will be taken by the CA thresher shark/swordfish and/or WA/OR/CA sablefish pot fishery is low. Accordingly, Criterion 3 is satisfied for both time frames analyzed in determining that mortality and serious injuries of the CA/OR/WA fin whale stock incidental to commercial fishing would have a negligible impact on the stock because of individual review of data regarding the stock, including increased growth rate of the stock, limited increases in serious injury and mortality due to the relevant fisheries, and the level of human-caused mortality and serious injury is below the estimated PBR.

The fishery-related mortality and serious injury from all commercial fisheries for the CA/OR/WA humpback

whale stock is estimated at 53.1% of PBR (of 11.3) for the 5-year average from 2007–2011, and 31.9% of PBR for the 14-year average from 1998–2011. A total of two humpback whales were observed, estimated or assumed to have either been killed or injured in the two fisheries considered in this authorization, the CA thresher shark/swordfish DGN fishery and WA/OR/CA sablefish pot fishery, which is a small portion of the stock's PBR, which is calculated using a recovery factor of 0.3. The minimum population size is 1,878 and is growing at a rate of about 4%/year which is equal to the default maximum growth rate for cetaceans (4%). Accordingly, Criterion 3 is satisfied for both time frames analyzed in determining that mortality and serious injuries of the CA/OR/WA humpback whale stock incidental to commercial fishing would have a negligible impact on the stock because of individual review of data regarding the stock, including increased growth rate of the stock, limited increases in serious injury and mortality due to the relevant fisheries, and the level of human-caused mortality and serious injury is below the estimated PBR.

The fishery-related mortality and serious injury from all commercial fisheries for the CA/OR/WA sperm whale stock is estimated at 66.7% of PBR (of 1.5) for the 5-year average from 2007–2011, and 33.3% of PBR for the 14-year average from 1998–2011. A total of three sperm whales were observed, estimated or assumed to have either been killed or injured in the CA thresher shark/swordfish DGN fishery since 1998 and none have interacted with the WA/OR/CA sablefish pot fishery. The most recent population abundance estimate from 2008 is the lowest to date, in sharp contrast to the highest abundance estimate obtained from 2001 and 2005 surveys. However, there is no reason to believe that the population has declined; the most recent survey likely reflects inter-annual variability with the study area. Sperm whale distribution and relative abundance may be correlated to the abundance of their main prey items and the population of the CA/OR/WA sperm whale stock has fluctuated since 1979/80 without apparent trend and appears relatively stable. The stock's PBR is calculated using a recovery factor of 0.1 (with a long term-average mortality and serious injury equal to PBR, 90% of the stock's net annual production would be reserved for recovery). The minimum population size is about 751 and is growing at a rate of about 2%/year which is one half of the default maximum growth rate for cetaceans (4%). Also, the infrequency of sperm whale interactions with the CA thresher shark/swordfish DGN fishery in the last 14 years (1998–2011) indicates that the likelihood that another sperm whale would be taken by this fishery is low (sperm whales have not interacted WA/OR/CA sablefish pot fishery). Thus, based on this information and the applicability of Criterion 3, NMFS determines that the mortality and serious injury incidental to commercial fisheries will have a negligible impact on the CA/OR/WA stock of sperm whales for both time frames analyzed.

In conclusion, based on the criteria outlined in 1999 (64 FR 28800), the 2011 Pacific SARs (Carretta *et al.* 2012) and the best scientific information and data available, NMFS has determined that for a period of up to three years, mortality and serious injury incidental to the CA thresher shark/swordfish DGN fishery and the WA/OR/CA sablefish pot fishery will have a negligible impact on the CA/OR/WA stock of sperm whales, the CA/OR/WA stock of humpback whales, and the CA/OR/WA stock of fin whales (*i.e.,* the total fisheries-related serious injury and mortality is greater than 0.1 PBR and less than PBR for both time periods and the populations of these stocks are considered to be stable or increasing). Therefore, these identified commercial fisheries within the range of the CA/OR/WA fin, humpback, and sperm whale stocks may be permitted subject to their individual review and the certainty of relevant data, and provided that the other provisions of section 101(a)(5)(E) are met.

Description of Fisheries

The following are the Federally-authorized fisheries classified as Category II in the 2011 LOF, which are known to seriously injure or kill ESA-listed marine mammals incidental to commercial fishing operations. Detailed descriptions of those fisheries can be found in the NMFS (2012a) Final Biological Opinion on the groundfish fishery management plan, dated December 7, 2012, for the fisheries addressed in that Biological Opinion; the NMFS (2012b) draft Biological Opinion for the CA thresher shark/swordfish DGN fishery (≥14 inch mesh; currently in preparation; the final SARs (Carretta *et al.* 2012; Allen and Angliss 2011); and the draft NID (*http://swr.nmfs.noaa.gov/*). Certain aspects of the fisheries may be altered due to reasonable and prudent alternatives included in each of the biological opinions; however, these changes in fishing operations are not expected to result in increased levels of mortality and serious injury of marine mammals, including threatened and endangered species. CA thresher shark/swordfish DGN fishery (≥14 inch mesh)

Participants in the CA thresher shark/swordfish DGN fishery (≥14 in mesh) are also required to have a valid permit issued annually by the California Department of Fish and Wildlife. In accordance with MMPA section 118(c), only those vessels in the CA thresher shark/swordfish DGN fishery (≥14 inch mesh) that have registered for a Marine Mammal Authorization Permit are authorized to take marine mammals incidental to their fishing operations. Vessels holding this permit must comply with the POCTRP and implementing regulations. Any vessel that violates regulations will be investigated. The estimate of the number of vessels in the fishery is a historical reference based upon the number of vessels that indicated intent to participate in the fishery and may not be an accurate estimate of the number of vessels actively engaged in fishing in any given year. The DGN fishery is a limited entry program, managed with gear, seasons, and area closures. The number of vessels participating in the CA thresher shark/swordfish DGN fishery (≥14 inch mesh) has decreased. In 2010, there were 73 permits issued, but currently there are only 27 active vessels (CDFG License and Revenue Branch, extracted July 14, 2011).

The CA thresher shark/swordfish DGN fishery targets swordfish and thresher shark. This fishery is a limited entry fishery with seasonal closures and gear restrictions. The CA thresher shark/swordfish DGN fishery operates outside of state waters to about 150 miles offshore ranging from the U.S./Mexico border in the south to the Oregon border in the north, depending on sea temperature conditions. Regulations restrict the fishery to waters outside 200 nm from February 1 through April 30, outside 75 nm from May 1 through August 14, and is allowed to fish inside 75 nm from August 15 through January 31. CA thresher shark/swordfish DGN vessels when targeting swordfish tend to set on warm ocean water temperature breaks, which do not appear along the California coast until late summer; therefore, because of these restrictions, vessels are not active during February, March, and April, and very little fishing effort occurs during the months of May, June, and July.

In 2001, a seasonal (15 August–15 November) area closure was implemented in the thresher shark/swordfish DGN fishery north of Point Conception, to protect leatherback

turtles that feed in the area and were observed entangled in previous fishing seasons. Additional seasonal/area closures in southern California have been established in the thresher shark/swordfish DGN fishery to protect loggerhead turtles during a forecast or occurring El Niño event during the months of June, July and/or August. Information on the number of active permit holders was obtained from the ''Status of the U.S. west coast fisheries for Highly Migratory Species through 2004; Stock Assessment and Fishery Evaluation'' report, available from the Pacific Fishery Management Council Web site (*www.pcouncil.org).*

The NMFS's Southwest Region has operated an at-sea observer program in the CA thresher shark/swordfish DGN fishery since July 1990 to the present, and the California Department of Fish and Wildlife had operated a DGN observer program from 1980–90. The objectives of the NMFS Observer Program are to record, among other things, information on non-target fish species and protected species interactions. Information regarding the thresher shark/swordfish DGN fishery interactions with listed marine mammal species was drawn from Observer Program records for the calendar years 1990–2011 (NMFS 2012). Observer coverage of the thresher shark/swordfish DGN fleet targets 20 percent of the annual sets made in the fishery, with close to 100 percent of net retrievals monitored on observed trips for, among other things, species identification and enumeration.

WA/OR/CA Sablefish Pot Fishery

The WA/OR/CA sablefish pot fishery targets sablefish using trapezoid, conical, or rectangular steel frame traps (NMFS 2005), wrapped with 3.5 inch nylon webbing. The fishery generally sets gear in waters past the 100 fathom curve off the west coast of the U.S. The fishery is managed under regulations implementing the West Coast Groundfish FMP developed by the Pacific Fishery Management Council. There are two separate trap fisheries for sablefish, limited entry and open access. The limited entry fishery is further divided into: (1) Vessels fishing in the limited entry fixed gear fishery with a limited entry permit endorsed for pot and/or longline gear, and (2) since 2011, vessels fishing in the limited entry trawl fishery with a limited entry permit endorsed for trawl gear but fishing with ''non-trawl'' gear including pot gear (called ''gear switching'' in the trawl fishery's Shore-based Individual Fishing Quota (IFQ) Program).

The primary fishery, limited entry, is composed of a three tier system of cumulative landing quotas within a restricted season, from April 1 to October 31. Permits were assigned to a tier based on landing history when the system originally began in 1998. There are 32 limited entry permits issued for the sablefish trap fishery on the U.S. west coast (NWFSC 2010). Fishing outside of the primary season or after fulfillment of tier quota is allowed subject to daily and weekly trip limits (NWFSC 2010). The limited entry permits are currently associated with vessels spread throughout the Pacific Northwest from Northern California through Washington. Up to three permits may be stacked for cumulative landings on one vessel; including both trap and longline gear endorsements (NWFSC 2010). Accounting for stacking of permits, there were twenty-four vessels using traps to target sablefish in the 2009 season, with seven of those vessels using traps only (NWFSC 2010). The other seventeen used a combination of traps and longline to catch their quota of sablefish.

In addition to the limited entry fixed gear fishery, a vessel registered to a limited entry groundfish permit endorsed for trawl gear may fish in the Shorebased IFQ Program using pot gear (NMFS 2012 West Coast Groundfish IFQ Fishery Catch Summary 2011: First Look. Agenda Item F.6.b, Supplemental NMFS Report, March 2012 Pacific Fishery Management Council meeting). Using a gear other than trawl gear to fish in the Shorebased IFQ Program is called ''gear switching.'' The Shorebased IFQ Program began in 2011 and operates year round. In 2011, nine percent of the IFQ fishing trips were made by vessels using pot gear.

The open access fishery is available to fishermen year round and is subject to weekly trip limits. The estimated number of current participants in the open access fishery is 309. NOAA's Northwest Fisheries Science Center estimates 123 fishermen, longline and trap combined, participated in the open access sector in 2009 based on a query of the fish ticket records in the PacFIN landings database (NWFSC 2010).

In California, a general trap permit is required for the open access sector for sablefish and gear is set outside 150 fathoms, with an average depth of 190 fathoms. South of Point Arguello, near Santa Barbara, the minimum depth for setting traps targeting sablefish is 200 fathoms. There is no depth requirement north of Point Arguello. Daily logbook reporting is required by the state. Multiple traps are connected to a common ground line, 5/8th inch nylon line, at depths between 100 and 375 fathoms up to 600 fathoms with an average of 190 fathoms in California (NMFS 2010). Traps are spaced on average 20 fathoms apart, with a range of 15 to 40 fathoms (NMFS 2005). Limited entry permit holders will commonly fish 20 to 30 traps per string, as opposed to open access fishermen who fish several smaller strings of one to eight strings with three to four traps per string (NMFS 2010), each with a float line and buoy stick.

Conclusions for Proposed Permit

Based on the above assessment and as described in the accompanying draft NID, NMFS concludes that the incidental mortality and serious injury from the CA thresher shark/swordfish DGN fishery (≥14 inch mesh) and the WA/OR/CA sablefish pot fishery will have a negligible impact on the CA/OR/WA stock of humpback whales, the CA/OR/WA stock of fin whales, and the CA/OR/WA stock of sperm whales. The National Environmental Policy Act (NEPA) requires Federal agencies to evaluate the impacts of alternatives for their actions on the human environment. The impacts on the human environment of continuing and modifying the CA thresher shark/swordfish DGN fishery (≥14 inch mesh) (as part of the Highly Migratory Species fisheries) and the WA/OR/CA sablefish pot fishery (as part of the West Coast groundfish fisheries), including the taking of threatened and endangered species of marine mammals, were analyzed in: the Pacific Fishery Management Council Highly Migratory Species Fishery Management Plan final environmental impact statement (August 2003); the Pacific Fishery Management Council Proposed Harvest Specifications and Management Measures for the 2013–2014 Pacific Coast Groundfish Fishery and Amendment 21–2 to the Pacific Coast Fishery Management Plan (September 2012); Risk assessment of U.S. West Coast groundfish fisheries to threatened and endangered marine species (NWFSC 2012); and in the Final Biological Opinion prepared for the West Coast groundfish fisheries (NMFS 2012a) and the draft Biological Opinion for the CA thresher shark/swordfish DGN fishery (≥14 inch mesh) (NMFS 2012b), currently in preparation, pursuant to the ESA. Because this proposed permit would not modify any fishery operation and the effects of the fishery operations have been evaluated fully in accordance with NEPA, no additional NEPA analysis is required for this permit. Issuing the proposed permit would have no additional impact to the

human environment or effects on threatened or endangered species beyond those analyzed in these documents. NMFS now reviews the remaining requirements to issue a permit to take the subject listed species incidental to the CA thresher shark/swordfish DGN fishery (≥14 inch mesh) and WA/OR/CA sablefish pot fisheries.

Recovery Plans

Recovery Plans for humpback whales, fin whales, and sperm whales have been completed (see *http://www.nmfs.noaa.gov/pr/recovery/plans.htm#mammals*). Accordingly, the requirement to have recovery plans in place or being developed is satisfied.

Vessel Registration

MMPA section 118(c) requires that vessels participating in Category I and II fisheries register to obtain an authorization to take marine mammals incidental to fishing activities. Further, section 118(c)(5)(A) provides that registration of vessels in fisheries should, after appropriate consultations, be integrated and coordinated to the maximum extent feasible with existing fisher licenses, registrations, and related programs. Participants in the CA thresher shark/swordfish DGN fishery (≥14 inch mesh) and WA/OR/CA sablefish pot fisheries already provide the information needed by NMFS to register their vessels for the incidental take authorization under the MMPA either through the federal groundfish limited entry permit process of the federal Vessel Monitoring System. Therefore, vessel registration for an MMPA authorization is integrated through those programs in accordance with MMPA section 118.

Monitoring Program

The CA thresher shark/swordfish DGN fishery (≥14 inch mesh) has been observed since the early 1990s. Levels of observer coverage vary over years but are adequate to produce reliable estimates of mortality and serious injury of listed species (*e.g.,* from 2000–2010, coverage ranged from 12.0 to 22.9 percent). As part of the West Coast groundfish fishery and Magnuson-Stevens Fishery Conservation and Management Act objectives, the WA/OR/CA sablefish pot fishery, as managed under the groundfish FMP, is observed at about 1–6% per year. Accordingly, as required by MMPA section 118, a monitoring program is in place.

Take Reduction Plans

Subject to available funding, MMPA section 118 requires the development and implementation of a Take Reduction Plan (TRP) in cases where a strategic stock interacts with a Category I or II fishery. The stocks considered for this permit are designated as strategic stocks under the MMPA because they are listed as threatened or endangered under the ESA. In 1996, a take reduction team (TRT) was convened to develop a TRP to address the incidental taking of several strategic stocks in the CA thresher shark/swordfish drift gillnet fishery. A POCTRP was implemented, through regulations, in October, 1997 (62 FR 51813) and has been in place ever since. These strategic stocks also interact with the WA/OR/CA sablefish pot/trap fishery and other Category II fisheries described above, and a potential TRP is in the development phase. The short- and long-term goals of a TRP are to reduce mortality and serious injury of marine mammals incidental to commercial fishing to levels below PBR and to a zero mortality rate goal (indicated by meeting the threshold for placement in the annual LOF Category III), respectively. MMPA section 118(b)(2) states that fisheries maintaining such mortality and serious injury levels are not required to further reduce their mortality and serious injury rates. However, the obligations to develop and implement a TRP are subject to the availability of funding. MMPA section 118(f)(3) (16 U.S.C. 1387(f)(3)) contains specific priorities for developing TRPs. NMFS has insufficient funding available to simultaneously develop and implement TRPs for all stocks that interact with Category I or Category II fisheries. As provided in MMPA section 118(f)(6)(A) and (f)(7), NMFS used the most recent SARs and LOF as the basis to determine its priorities for establishing TRTs and developing TRPs. Through this process, NMFS evaluated the CA/OR/WA stocks of humpback, fin, and sperm whales, and identified them as lower priorities compared to other marine mammal stocks and fisheries for establishing TRTs, based on population trends of each stock and mortality and serious injury levels incidental to commercial fisheries. In addition, NMFS is currently collecting data to categorize fixed gear fisheries and assess their risk to large whales off the U.S. west coast. Accordingly, given these factors and NMFS' priorities, implementation of the developing TRP for the WA/OR/CA sablefish pot trap fishery and other similar Category II fisheries will be deferred under section 118 as other stocks/fisheries are a higher priority for any available funding for establishing new TRPs.

As noted in the summary above, all of the requirements to issue a permit to the following Federally-authorized fisheries have been satisfied: The CA thresher shark/swordfish DGN fishery (≥14 inch mesh) and WA/OR/CA sablefish pot fishery. Accordingly, NMFS proposes to issue a permit to participants in these Category II fisheries for the taking of CA/OR/WA humpback whales, CA/OR/WA fin whales, and CA/OR/WA sperm whales incidental to the fisheries' operations. As noted under MMPA section 101(a)(5)(E)(ii), no permit is required for vessels in Category III fisheries. For incidental taking of marine mammals to be authorized in Category III fisheries, any injuries or mortality must be reported to NMFS. NMFS solicits public comments on the proposed permit and the preliminary determinations supporting the permit.

Dated: May 3, 2013.

Helen M. Golde,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2013–10913 Filed 5–7–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2013–0025]

Proposed Collection; Comment Request

AGENCY: Department of Defense, Department of the Air Force, Air Force Personnel Center Services Directorate (AFPC/SV).

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995,* the Air Force Personnel Center Services Directorate announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 8, 2013.

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.

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 AFPC/SVI–PM 3515 S. General McMullen Port San Antonio, TX 78241–3420 or call (210) 395–9349.

Title; Associated Form; and OMB Number: Golf Enterprise Solution (GES); automated information system (AIS); OMB Control Number 0701–TBD.

Needs and Uses: The information collection requirement is to obtain golf patron information for tee-time reservations, annual green fee dues, to send out emails, and for promotional mailers. This information is obtained electronically when a golf patron comes in to a golf course or online when a tee-time is scheduled online. There are no forms that have been generated for GES; all of the information is maintained within the point of sale (POS) & all of the electronic data resides in a secure, federal cloud. If the information was not collected, this would make daily business transactions difficult at the golf courses.

Affected Public: Individuals or households.

Annual Burden Hours: 1,667.

Number of Respondents: 50,000.

Responses per Respondent: 1.

Average Burden per Response: 2 minutes.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

Respondents are golf patrons who provide business to the Air Force Golf Courses. The information is used to determine how much the golf patron has to pay (based on class and rank), schedule tee times, set-up annual green fee memberships, participate in promotional emails and mailers, and to reserve golf carts and lockers. The information is obtained electronically through the point of sale (POS) or online through the online tee sheet. The information will only need to be collected once; the POS will store the data for future use. The only time the information will be obtained again is if the information of the golf patron has changed and needs to be updated.

Dated: May 2, 2013.

Aaron Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2013–10863 Filed 5–7–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2013–0019]

Proposed Collection; Comment Request

AGENCY: Department of Defense/Department of the Air Force/673 Civil Engineer Natural Cultural Resources and Planning Section, DoD.

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995,* the 673 Civil Engineer Natural Cultural Resources and Planning section announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 8, 2013.

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.

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 673 Civil Engineer Natural Cultural Resources and Planning section, 7210 12th Street, Joint Base Elmendorf-Richardson, Alaska 99506–2620, ATTN: Mark Sledge, Joint Base Elmendorf-Richardson, Alaska 99506–2620, or call 673 Civil Engineer Natural Cultural Resources and Planning section, at 907–552–8609.

Title; Associated Form; and OMB Number: Recreational Access Permit System; OMB Control Number 0701–TBD.

Needs and Uses: The information collection requirement is necessary to track use of recreational resources controlled by the government by virtue of location. Logs used to de-conflict the recreational use of resources against military movements, military operational exercises and military drills; several live fire ranges are intertwined with recreational areas. The Recreational Access Permit System will detail when areas are not authorized for recreational use due to military requirements as well as provide contact listings in the event recreational users need to be notified of changes to the military activities schedule.

Affected Public: Individuals or households.

Annual Burden Hours: 2000.

Number of Respondents: 8000.

Responses per Respondent: 1.

Average Burden per Response: 15 minutes.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

Respondents are recreational land users seeking to use recreational resources controlled by the government by virtue of location. The information collected is to ensure the safety of individuals using land which is concurrently used for military training; including live fire ranges. The system

will notify users when recreational lands are not available for use and allow for de-confliction of use for multipurpose land on military installations. The system will also act as a last known location log should individuals using recreational lands become missing while using the access areas.

Dated: May 2, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–10872 Filed 5–7–13; 8:45 am]

BILLING CODE 5001–05–P

DEPARTMENT OF DEFENSE

Department of the Air Force

U.S. Air Force Scientific Advisory Board; Notice of Meeting

AGENCY: U.S. Air Force Scientific Advisory Board, Department of the Air Force.

ACTION: Meeting notice.

SUMMARY: Under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150, the Department of Defense announces that the United States Air Force Scientific Advisory Board (SAB) meeting will take place 25 June 2013 at the Secretary of the Air Force Technical and Analytical Support Conference Center, 1550 Crystal Drive, Arlington, VA 22202. The meeting will be from 7:45 a.m.–4:45 p.m. on Tuesday, 25 June 2013, with the sessions from 7:45 a.m.–09:45 a.m. open to the public.

The purpose of this Air Force Scientific Advisory Board quarterly meeting is to discuss and deliberate on the findings and recommendations of the FY13 SAB studies covering airborne networking and communications in a contested environment, electro-optical and laser threat warning/countermeasures, and micro-satellite mission applications. The draft FY14 SAB study topics and potential sites for the FY14 Spring Board quarterly meeting will also be discussed.

In accordance with 5 U.S.C. 552b, as amended, and 41 CFR 102–3.155, the Administrative Assistant of the Air Force, in consultation with the Air Force General Counsel, has agreed that the public interest requires some sessions of the United States Air Force Scientific Advisory Board meeting be closed to the public because they will discuss information and matters covered by section 5 U.S.C. 552b(c)(1).

Any member of the public wishing to provide input to the United States Air Force Scientific Advisory Board should submit a written statement in accordance with 41 CFR 102–3.140(c) and section 10(a)(3) of the Federal Advisory Committee Act and the procedures described in this paragraph. Written statements can be submitted to the Designated Federal Officer at the address detailed below at any time. Statements being submitted in response to the agenda mentioned in this notice must be received by the Designated Federal Officer at the address listed below at least five calendar days prior to the meeting which is the subject of this notice. Written statements received after this date may not be provided to or considered by the United States Air Force Scientific Advisory Board until its next meeting. The Designated Federal Officer will review all timely submissions with the United States Air Force Scientific Advisory Board Chairperson and ensure they are provided to members of the United States Air Force Scientific Advisory Board before the meeting that is the subject of this notice.

FOR FURTHER INFORMATION CONTACT: The United States Air Force Scientific Advisory Board Executive Director and Designated Federal Officer, Lt Col Darek Lincoln, 240–612–5502, United States Air Force Scientific Advisory Board, 1500 West Perimeter Road, Ste. #3300, Joint Base Andrews, MD 20762, *Derek.Lincoln@pentagon.af.mil.*

Henry Williams Jr,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2013–10912 Filed 5–7–13; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF EDUCATION

Applications for New Awards; School Leadership Program

AGENCY: Office of Innovation and Improvement, Department of Education.

ACTION: Notice.

Overview Information:

School Leadership Program.

Notice inviting applications for new awards for fiscal year (FY) 2013.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.363A.

DATES:

Applications Available: May 8, 2013.

Deadline for Notice of Intent to Apply: June 7, 2013.

Date of Pre-Application Meeting: May 22, 2013. Further information will be available at: *www2.ed.gov/programs/leadership/applicant.html.*

Deadline for Transmittal of Applications: July 8, 2013.

Deadline for Intergovernmental Review: September 5, 2013.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The School Leadership Program (SLP) assists high-need local educational agencies (LEAs) in recruiting, training, and supporting principals (including assistant principals) by providing—

- Financial incentives to aspiring new principals (teachers or individuals from other fields who want to become principals);
- Stipends to principals who mentor new principals;
- Professional development programs that focus on instructional leadership and management; and
- Other incentives that are appropriate and effective in retaining new principals.

Background:

The goal of the SLP is to increase student achievement by investing in innovative projects that prepare aspiring principals and provide professional development to current principals (including current assistant principals) to foster mastery of core leadership skills. To this end, the Department encourages applicants under this competition to propose projects that will implement pre- and in-service programs that produce the most highly qualified school leaders.

Studies show that there is no overall shortage of candidates with the credentials that States require for school principals. However, those same studies indicate that most of these candidates acquired their credentials in order to obtain salary increases or attain an advanced degree, not necessarily because of a commitment to become principals.[1] And, when credentialed candidates do seek to become principals, some lack the readiness to meet the demands of the position. In fact, many district leaders and policy-makers are critical of preparation programs that lack rigorous screening and selection entry requirements, courses that are not aligned with standards of practice, and insufficient clinical experiences for candidates.[2]

[1] Roza, M., Celio, M.B., Harvey, J., & Wishon, S. (January 2003). A Matter of Definition: Is There Truly a Shortage of School Principals? A Report to the Wallace—Reader's Digest Fund.

[2] Hale, E. L., & Moorman, H.N. (September 2003). Preparing School Principals: A National Perspective on Policy and Program Innovations. Washington, DC: Institute for Educational Leadership.

Furthermore, once credentialed individuals become principals, they are often not provided the necessary support and development opportunities that will enable them to shape a strong professional community and collective responsibility for student learning. In terms of professional development, too often these programs are not aligned with principals' needs, fragmented, episodic and not sustained, lacking in rigor, and not designed to allow for any assessment of impact.

Consequently, both novice and experienced principals (including assistant principals) lack the necessary skills to respond to the growing demands of their positions, which include evaluating, supporting, and developing teachers and implementing effective organizational processes. Moreover, as the effect of leaders on student achievement becomes more evident, high-quality professional development programs are increasingly critical.

Unfortunately, there is limited evidence that demonstrates the effect of principal preparation and professional development programs' impact on teaching and learning. Therefore, through this competition, we encourage applicants to address the challenges of preparing and supporting principals by creating or enhancing projects that contribute to the limited body of high-quality evidence on principal preparation, professional development for principals, or both.

More specifically, under the selection criteria, applicants are encouraged to include an evaluation plan that is likely to produce valid, reliable, and rigorous evidence of the SLP-funded project's impact on producing effective principals, as measured, at least in part, using student outcome data, where data is available.

Given the pre-service and in-service challenges that so many principals face, we are including two invitational priorities to promote high-quality professional development for principals and to identify evidence of effectiveness of principal preparation or professional development programs. Invitational priority one encourages applicants to design projects that will provide ongoing support and development of principals (including assistant principals) to increase principal effectiveness. Invitational priority two seeks to identify project designs that address principal preparation, professional development, or both and that are supported by moderate evidence of effectiveness (as defined in this notice). Through these invitational priorities we encourage applicants to identify practices, strategies, and program models that build and enhance school leader capacity to positively impact teaching and learning. Addressing the invitational priorities will not give an applicant an advantage over another applicant that does not choose to respond to the invitational priorities. However, we hope applicants will consider the invitational priorities in developing their applications.

Priority: Under this competition we are particularly interested in applications that address the following priorities.

Invitational Priorities: For FY 2013 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, these priorities are invitational priorities. Under 34 CFR 75.105(c)(1), we do not give an application that meets these invitational priorities a competitive or absolute preference over other applications.

These priorities are:

Invitational Priority 1—Building Leadership Capacity.

Projects that implement professional development for current principals (including assistant principals), especially in schools that the State educational agency (SEA) has identified as persistently lowest-achieving schools, (as defined in this notice) or in schools that the SEA has identified in accordance with its approved ESEA flexibility request as priority schools or focus schools (as defined in this notice), to: (1) Help them master essential school leadership skills, such as evaluating and providing feedback to teachers, analyzing student data, developing school leadership teams, and creating a positive school environment; and (2) enable them to support instruction in their schools aligned to college- and career-ready standards.

Invitational Priority 2—Supporting Practices and Strategies for Which There Is Moderate Evidence of Effectiveness.

Projects that provide principal preparation, professional development, or both that are supported by moderate evidence of effectiveness (as defined in this notice).

Definitions:

Focus school means a Title I school in the State that, based on the most recent data available, is contributing to the achievement gap in the State. The total number of focus schools in a State must equal at least 10 percent of the Title I schools in the State. A focus school is a school that has the largest within-school gaps between the highest-achieving subgroup or subgroups and the lowest-achieving subgroup or subgroups or, at the high school level, has the largest within-school gaps in graduation rates; or a school that has a subgroup or subgroups with low achievement or, at the high school level, low graduation rates.

An SEA must also identify as a focus school a Title I high school with a graduation rate less than 60 percent over a number of years that is not identified as a priority school.

These determinations must be based on the achievement and lack of progress over a number of years of one or more subgroups of students identified in section 1111(b)(2)(C)(v)(II) of the Elementary Secondary Education Act, as amended (ESEA), in terms of proficiency on the statewide assessments that are part of the SEA's differentiated recognition, accountability, and support system, combined, or, at the high school level, graduation rates for one or more subgroups.

Large sample means a sample of 350 or more students (or other single analysis units) who were randomly assigned to a treatment or control group, or 50 or more groups (such as classrooms or schools) that contain 10 or more students (or other single analysis units) and that were randomly assigned to a treatment or control group.

Moderate evidence of effectiveness means one of the following conditions is met:

(1) There is at least one study of the effectiveness of the process, product, strategy, or practice being proposed that meets the What Works Clearinghouse (WWC) Evidence Standards without reservations;[3] finds a statistically significant favorable impact on a relevant outcome (as defined in this notice) (with no statistically significant unfavorable impacts on that outcome for relevant populations in the study or in other studies of the intervention reviewed by and reported on by the WWC); and includes a sample that overlaps with the populations or settings proposed to receive the process, product, strategy, or practice.

(2) There is at least one study of the effectiveness of the process, product, strategy, or practice being proposed that meets the WWC Evidence Standards with reservations;[4] finds a statistically significant favorable impact on a relevant outcome (as defined in this

[3] *See* WWC Procedures and Standards Handbook (Version 2.1, September 2011), which can currently be found at: *http://ies.ed.gov/ncee/wwc/DocumentSum.aspx?sid=19.*

[4] *See* WWC Procedures and Standards Handbook (Version 2.1, September 2011), which can currently be found at: *http://ies.ed.gov/ncee/wwc/DocumentSum.aspx?sid=19.*

notice) (with no statistically significant unfavorable impacts on that outcome for relevant populations in the study or in other studies of the intervention reviewed by and reported on by the WWC); includes a sample that overlaps with the populations or settings proposed to receive the process, product, strategy, or practice; and includes a large sample (as defined in this notice) and a multi-site sample (as defined in this notice). (**Note:** Multiple studies can cumulatively meet the large and multi-site sample requirements as long as each study meets the other requirements in this paragraph.)

Multi-site sample means more than one site, where site can be defined as an LEA, locality, or State.

Persistently lowest-achieving school means, as determined by the State: (1) Any Title I school in improvement, corrective action, or restructuring that is (a) among the lowest-achieving five percent of Title I schools in improvement, corrective action, or restructuring or the lowest-achieving five Title I schools in improvement, corrective action, or restructuring in the State, whichever number of schools is greater; or (b) a high school that has had a graduation rate as defined in 34 CFR 200.19(b) that is less than 60 percent over a number of years; and (2) any secondary school that is eligible for, but does not receive, Title I funds that is (a) among the lowest-achieving five percent of secondary schools or the lowest-achieving five secondary schools in the State that are eligible for, but do not receive, Title I funds, whichever number of schools is greater; or (b) a high school that has had a graduation rate as defined in 34 CFR 200.19(b) that is less than 60 percent over a number of years.

Note: For the purposes of this competition, the Department considers schools that are identified as Tier I or Tier II schools under the SIG Program (see 75 FR 66363) as part of a State's approved FY 2009, FY 2010, or FY 2011 application to be persistently lowest-achieving schools. A list of these Tier I and Tier II schools can be found on the Department's Web site at *http://www2.ed.gov/programs/sif/index.html.*

Priority school means a school that, based on the most recent data available, has been identified as among the lowest-performing schools in the State. The total number of priority schools in a State must be at least five percent of the Title I schools in the State. A priority school is a—

- School among the lowest five percent of Title I schools in the State based on the achievement of the ''all students'' group in terms of proficiency on the statewide assessments that are part of the SEA's differentiated recognition, accountability, and support system, combined, and that has demonstrated a lack of progress on those assessments over a number of years in the ''all students'' group;
- Title I-participating or Title I-eligible high school with a graduation rate less than 60 percent over a number of years; or
- Tier I or Tier II school under the School Improvement Grant (SIG) Program that is using SIG funds to implement a school intervention model.

Relevant outcome means the student outcome or outcomes (or the ultimate outcome if not related to students) that the proposed project is designed to improve, consistent with the specific goals of a program.

Program Authority: 20 U.S.C. 6651(b).

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 84, 86, 97, 98, and 99. (b) The Education Department suspension and debarment regulations in 2 CFR part 3485.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: $14,800,000.

Estimated Range of Awards: $750,000-$1,000,000.

Estimated Average Size of Awards: $850,000.

Estimated Number of Awards: 14–17.

Note: The Department is not bound by any estimates in this notice and may elect to forward fund awards for a project period of up to 60 months, thereby decreasing the number of estimated awards.

Project Period: Up to 60 months (subject to availability of funds).

III. Eligibility Information

1. *Eligible Applicants:* High-need LEAs; consortia of high-need LEAs; and partnerships of high-need LEAs, nonprofit organizations (which may be community- or faith-based organizations), and institutions of higher education.

''High-need LEA'' (as defined in section 2102(3) of the ESEA) means an LEA—

(a)(1) That serves not fewer than 10,000 children from families with incomes below the poverty line, or (2) for which not less than 20 percent of the children served by the LEA are from families with incomes below the poverty line; and

(b) For which there is (1) a high percentage of teachers not teaching in the academic subjects or grade levels the teachers were trained to teach, or (2) a high percentage of teachers with emergency, provisional, or temporary certification or licensing.

So that the Department can confirm the eligibility of the LEAs that applicants propose to serve, applicants must include information in their applications that demonstrates that each participating LEA in the project is a high-need LEA. This information must be based on the most recent available data on the number of children that the LEA serves from families with incomes below the poverty line. When presenting evidence to support that each participating LEA is a high-need LEA, an applicant must consider the following:

The Department is not aware of any reliable data that are available to LEAs—other than data periodically gathered by the U.S. Census Bureau—that would show that an LEA serves the required number or percentage of children (individuals ages 5 through 17) from families below the poverty line (as defined in section 9101(33) of the ESEA).

Note: The data that many LEAs collect on the number or percentage of children eligible for free- and reduced-priced meal subsidies may not be used to satisfy the requirements under component (a) of the ESEA definition of ''high-need LEA.'' Those data do not reflect children from families with incomes below the poverty line, as that term is defined in section 9101(33) of the ESEA.

Therefore, absent a showing of alternative LEA data that reliably show the number of children from families with incomes below the poverty line that are served by the LEA, the eligibility of an LEA as a high-need LEA under component (a) would be determined on the basis of the most recent U.S. Census Bureau data. U.S. Census Bureau data are available for all school districts with geographic boundaries that existed when the U.S. Census Bureau collected its information. The link to the Census Bureau data is: *www.census.gov/hhes/www/saipe/data/index.html.* The Department also makes these data available on its Web site at: *www.ed.gov/programs/lsl/eligibility.html.* (Although the Department has posted this listing specifically for the Improving Literacy through School Libraries program, these same data apply to the ESEA definition of a ''high-need LEA'' used for purposes of determining eligibility under the SLP.)

With regard to component (b)(1) of the ESEA definition of ''high-need LEA,'' the Department interprets the phrase ''a high percentage of teachers not teaching in the academic subjects or grade levels that the teachers were trained to teach'' as being equivalent to ''a high percentage of teachers teaching out of field.'' We expect that LEAs that rely on component (b)(1) of the ESEA definition of ''high-need LEA'' will choose to address why they believe that they have a high percentage of teachers teaching out of field rather than try to provide the data needed to show the percentage of teachers not teaching in the academic subjects or grade levels they were trained to teach. The Department is not aware of any specific data that would demonstrate a ''high percentage'' of teachers teaching out of field (or a high percentage of teachers not teaching in the academic subjects or grade levels they were trained to teach). Accordingly, the Department will review this aspect of an LEA's proposed eligibility on a case-by-case basis.

To decrease the level of uncertainty, an applicant may choose instead to demonstrate that each participating LEA meets the eligibility test for a high-need LEA under component (b)(2) of the ESEA definition. For component (b)(2), to demonstrate a ''high percentage'' of teachers with emergency, provisional, or temporary certification or licensing, an applicant would provide the percentage of teachers on waivers of State certification or licensure requirements. The Department would expect that an LEA with over 1.1 percent of its teachers having emergency, provisional, or temporary certification or licensing (i.e., teachers on waivers) has a ''high percentage.'' This percentage comes from data that States reported to the Secretary under section 207 of the Higher Education Act of 1965, as amended by the previous reauthorization, Higher Education Amendments of 1998. The most recent report available that contains this information is the Secretary's 2010 report, which is available at: *http://www2.ed.gov/about/reports/annual/teachprep/2011-title2report.pdf.*

The eligibility of LEAs for which data needed to implement section 2103(2) of the ESEA may not exist, such as newly formed LEAs or schools funded by the Bureau of Indian Education, will be determined on a case-by-case basis based on the best available data the applicant includes with its application.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the Internet or from the Education Publications Center (ED Pubs). To obtain a copy via the Internet, use the following address: *www.ed.gov/fund/grant/apply/grantapps/index.html.* To obtain a copy from ED Pubs, write, fax, or call the following: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *www.EDPubs.gov* or at its email address: *edpubs@inet.ed.gov.*

If you request an application from ED Pubs, be sure to identify this program or competition as follows: CFDA number 84.363A.

Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting the person or team listed under *Accessible Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this program.

Notice of Intent to Apply: The Department will be able to develop a more efficient process for reviewing grant applications if it has a better understanding of the number of entities that intend to apply for funding under this program. Therefore, the Secretary strongly encourages each potential applicant to notify the Department by sending a short email message indicating the applicant's intent to submit an application for funding. The email need not include information regarding the content of the proposed application, only the applicant's intent to submit it. This email notification should be sent to Tyra Stewart at: *schoolleadershipmatters@ed.gov.*

Applicants that fail to provide this email notification may still apply for funding.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. Applicants are strongly encouraged to limit the application narrative to the equivalent of no more than 50 single-sided pages, using the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the page limit does apply to all of the application narrative section (Part III).

3. *Submission Dates and Times:* Applications Available: May 8, 2013. Deadline for Notice of Intent to Apply: June 7, 2013. Date of Pre-Application Meeting: May 22, 2013. Further information will be available at: *www2.ed.gov/programs/leadership/applicant.html.* Deadline for Transmittal of Applications: July 8, 2013.

Applications for grants under this program must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV. 7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice. Deadline for Intergovernmental Review: Sept. 5, 2013.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal

Programs under Executive Order 12372 is in the application package for this program.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, Central Contractor Registry, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the Central Contractor Registry (CCR)—and, after July 24, 2012, with the System for Award Management (SAM), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active CCR or SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one business day.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow 2–5 weeks for your TIN to become active.

The CCR or SAM registration process may take five or more business days to complete. If you are currently registered with the CCR, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days to complete. Information about SAM is available at SAM.gov.

In addition, if you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined at the following Grants.gov Web page: *www.grants.gov/applicants/get_registered.jsp.*

7. *Other Submission Requirements:* Applications for grants under this program must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.* Applications for grants under the School Leadership Program, CFDA number 84.363A, must be submitted electronically using the Governmentwide Grants.gov Apply site at *www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement and submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for the School Leadership Program at *www.Grants.gov.* You must search for the downloadable application package for this program by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.363, not 84.363A).

Please note the following:

- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.
- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this program to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov under News and Events on the Department's G5 system home page at *www.G5.gov.*
- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.
- You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- You must upload any narrative sections and all other attachments to your application as files in a PDF (Portable Document) read-only, non-modifiable format. Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF or submit a password-protected file, we will not review that material.
- Your electronic application must comply with any page-limit requirements described in this notice.
- After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by email. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (a Department-specified identifying number unique to your application).
- We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the

Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the Grants.gov system;

and

- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Tyra Stewart, U.S. Department of Education, 400 Maryland Avenue SW., Room 4C111, Washington, DC 20202–5950. FAX: (202) 401–8466.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.* If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address:

U.S. Department of Education,
Application Control Center,
Attention: (CFDA Number 84.363A),
LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery.* If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address:

U.S. Department of Education,
Application Control Center,
Attention: (CFDA Number 84.363A),
550 12th Street SW., Room 7041,
Potomac Center Plaza, Washington,
DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program are from 34 CFR 75.210. The maximum score for all of the selection criteria is 100 points. The maximum score for each criterion is indicated in parentheses. Each criterion also includes the factors that the reviewers will consider in determining how well an application meets the criterion. Any notes following a selection criterion are intended to provide guidance to help applicants in preparing their applications only, and are not statutory or regulatory requirements for this competition.

Note: In responding to the selection criteria, applicants should keep in mind that peer reviewers may consider only the information provided in the written application when scoring and commenting on the application. Therefore, applicants should draft their response with the goal of helping peer reviewers understand the purpose of the proposed project, as well as the expected outcomes of the project if it is successful.

The criteria are as follows:

A. *Quality of the project design* (up to 45 points). The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers the following factors:

1. The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable.

2. The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs.

3. The extent to which the proposed project is part of a comprehensive effort to improve teaching and learning and support rigorous academic standards for students.

4. The extent to which the design for implementing and evaluating the proposed project will result in information to guide possible replication of project activities or strategies, including information about the effectiveness of the approach or strategies employed by the project.

Note: The Secretary encourages applicants to clearly articulate how the proposed project will support principals and assistant principals in fostering school conditions that support effective teaching and learning that lead to improved student outcomes.

B. *Quality of the project evaluation* (up to 15 points). The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers the following factors:

1. The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible.

2. The extent to which the methods of evaluation provide for examining the effectiveness of project implementation strategies.

3. The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

Note: Applicants are encouraged to develop a logic model, that is, a well-conceptualized framework that identifies key components of the proposed intervention and describes the relationship among the key components and outcomes. Applicants are also encouraged to ensure that they have devoted sufficient resources to support the implementation of their evaluation plan.

C. *Significance* (up to 25 points). The Secretary considers the significance of the proposed project. In determining the significance of the proposed project, the Secretary considers the following factors:

1. The potential contribution of the proposed project to increased knowledge or understanding of educational problems, issues, or effective strategies.

2. The likelihood that the proposed project will result in system change or improvement.

3. The importance or magnitude of the results or outcomes likely to be attained by the proposed project, especially improvements in teaching and student achievement.

D. *Quality of the management plan* (up to 15 points). The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

1. The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

2. The adequacy of procedures for ensuring feedback and continuous improvement in the operation of the proposed project.

2. *Review and Selection Process:* The Department will screen applications submitted in accordance with the requirements in this notice, and will determine which applications have met eligibility and other statutory requirements. Applications that do not meet the eligibility criteria will not be reviewed.

The Department will use independent peer reviewers with various backgrounds and professions, including teachers and principals, college and university educators, researchers and evaluators, grant makers and managers, and others with education expertise. The Department will thoroughly screen all reviewers for conflicts of interest to ensure a fair and competitive review process.

Reviewers will read, prepare a written evaluation of, and score the applications assigned to their panel, using the selection criteria provided in this notice.

We remind potential applicants that, in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Special Conditions:* Under 34 CFR 74.14 and 80.12, the Secretary may impose special conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 34 CFR part 74 or 80, as applicable; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170, should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on

reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Performance Measures:* The Secretary has established five performance measures for assessing the effectiveness of the SLP. The SLP performance measures are:

(1) The percentage of program graduates who are certified to become a principal or assistant principal.

(2) The percentage of program graduates who are certified and hired as a principal or assistant principal in a high-need LEA.

(3) The percentage of program graduates certified through the program who are hired as a principal or assistant principal in a high-need LEA and who remain in that position for at least two years.

(4) The percentage of principals and assistant principals who complete the SLP-funded professional development program and whose schools demonstrate positive change, no change, or negative change based on pre- and post-school site measures, of which one measure must include, if available, student growth (e.g., at least one grade level in an academic year).

(5) The percentage of program graduates who are rated ''effective'' or ''highly effective'' as measured by a U.S. Department of Education program approved principal evaluation system, if available.

Note: Applicants that receive funding under this program will be required to collect and submit data on the measures that are aligned to the project design in the annual performance report for each performance period. Specifically, for performance measure 4, grantees may include school site measures such as: Student disciplinary actions, teacher attendance, parent engagement, teachers rated ''effective'' or ''highly effective,'' or other school climate measures. For performance measure 5, where available, we are interested in collecting the percentage of SLP graduates who are rated ''effective'' or ''highly effective'' after completing the SLP funded professional development program for current principals or after one year in the position as principals for participants that became certified through the SLP funded project using a principal evaluation that has met the requirements and has been approved by programs such as: Race to the Top, ESEA Flexibility, School Improvement Grants, or the FY 2012 Teacher Incentive Fund principal evaluation system requirements. If a system is not yet approved by one of these programs we will determine appropriate data collection on a case-by-case basis.

5. *Continuation Awards:* In making a continuation award, the Secretary may consider, under 34 CFR 75.253, the extent to which a grantee has made ''substantial progress toward meeting the objectives in its approved application.'' This consideration includes the review of a grantee's progress in meeting the targets and projected outcomes in its approved application, and whether the grantee has expended funds in a manner that is consistent with its approved application and budget. In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Tyra Stewart, U.S. Department of Education, 400 Maryland Avenue SW., Room 4C111, Washington, DC 20202–5960. Telephone: (202) 260–1847, or by email: *Schoolleadershipmatters@ed.gov.*

If you use a TDD or TTY, call the Federal Relay Service, toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: May 3, 2013.

James H. Shelton, III,

Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 2013–10980 Filed 5–7–13; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–196–D]

Application to Export Electric Energy; ALLETE, Inc., d/b/a Minnesota Power

AGENCY: Office of Electricity Delivery and Energy Reliability, DOE.

ACTION: Notice of Application.

SUMMARY: ALLETE, Inc., d/b/a Minnesota Power (Minnesota Power) has applied to renew its authority to transmit electric energy from the United States to Canada pursuant to section 202(e) of the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before June 7, 2013.

ADDRESSES: Comments, protests, or motions to intervene should be addressed to: Lamont Jackson, Office of Electricity Delivery and Energy Reliability, Mail Code: OE–20, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585–0350. Because of delays in handling conventional mail, it is recommended that documents be transmitted by overnight mail, by electronic mail to *Lamont.Jackson@hq.doe.gov,* or by facsimile to 202–586–8008.

FOR FURTHER INFORMATION CONTACT: Lamont Jackson (Program Office) at 202–586–0808, or by email at *Lamont.Jackson@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: Exports of electricity from the United States to a foreign country are regulated by the Department of Energy (DOE) pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b), 7172(f)) and require authorization under section 202(e) of the Federal Power Act (16 U.S.C. 824a(e)).

On June 4, 2008, DOE issued Order No. EA–196–C, which authorized Minnesota Power to transmit electric energy from the United States to Canada as a power marketer for a five-year term using existing international transmission facilities. That authority expires on June 4, 2013. On April 25, 2013, Minnesota Power filed an application with DOE for renewal of the export authority contained in Order No. EA–196–C for an additional five-year term.

In its application, Minnesota Power states that it owns electric generation and transmission facilities and sells and distributes electricity within its northern Minnesota service territory. The electric energy that Minnesota Power proposes to export to Canada would be surplus energy purchased

from electric utilities and other entities within the United States. The existing international transmission facilities to be utilized by Minnesota Power have previously been authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's (FERC) Rules of Practice and Procedures (18 CFR 385.211). Any person desiring to become a party to these proceedings should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214). Five copies of such comments, protests, or motions to intervene should be sent to the address provided above on or before the date listed above.

Comments on the Minnesota Power application to export electric energy to Canada should be clearly marked with OE Docket No. EA–196–D. An additional copy is to be provided directly to Christopher D. Anderson, Associate General Counsel, ALLETE, Inc, 30 West Superior Street, Duluth, MN 55802. A final decision will be made on this application after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after a determination is made by DOE that the proposed action will not have an adverse impact on the sufficiency of supply or reliability of the U.S. electric power supply system.

Copies of this application will be made available, upon request, for public inspection and copying at the address provided above, by accessing the program Web site at *http://energy.gov/node/11845,* or by emailing Angela Troy at *Angela.Troy@hq.doe.gov*.

Issued in Washington, DC, on May 2, 2013.

Jon Worthington,

Deputy Assistant Secretary, Office of Electricity Delivery and Energy Reliability.

[FR Doc. 2013–10918 Filed 5–7–13; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC13–13–000]

Commission Information Collection Activities (FERC Form 580); Comment Request; Revision

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, 44 USC 3506(c)(2)(A), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC Form No. 580 (Interrogatory on Fuel and Energy Purchase Practices).

DATES: Comments on the collections of information are due July 8, 2013.

ADDRESSES: You may submit comments (identified by Docket No. IC13–13–000) by either of the following methods:

- eFiling at Commission's Web site: *http://www.ferc.gov/docs-filing/efiling.asp*.
- *Mail/Hand Delivery/Courier:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp*. For user assistance contact FERC Online Support by email at *ferconlinesupport@ferc.gov*, or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp*.

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov*, telephone at (202) 502–8663, and fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Title: Interrogatory on Fuel and Energy Purchase Practices (FERC Form No. 580).

OMB Control No.: 1902–0131.

Type of Request: Three-year approval of the FERC Form No. 580.

Abstract: FERC Form No. 580 is collected in even numbered years. The Public Utility Regulatory Policies Act (PURPA) [1] amended the Federal Power Act (FPA) and directed the Commission to make comprehensive biennial reviews of certain matters related to automatic adjustment clauses (AACs) in wholesale rate schedules used by public utilities subject to the Commission's jurisdiction. Specifically, the Commission is required to examine whether the clauses effectively provide the incentives for efficient use of resources and whether the clauses reflect only those costs that are either ''subject to periodic fluctuations'' or ''not susceptible to precise determinations'' in rate cases prior to the time the costs are incurred.

The Commission is also required to review the practices of each public utility under AACs ''to insure efficient use of resources under such clauses.'' [2] In response to the PURPA directive, the Commission (Docket Number IN79–6–000) established an investigation. Beginning in 1982, the Commission collected ''Interrogatory on Fuel and Energy Purchase Practices'' data every other year.

In 2010, the Commission redesigned the form to collect the information electronically through use of a standard form. Based on filer comments in response to the new electronic form used in the 2010 and 2012 collections, FERC recommends the following changes to the form:

Question 1

—Repair the email field to eliminate error messages.

Question 2

—Add a column labeled ''Is this AAC a fuel adjustment clause?''
—Add a column labeled ''Tariff volume number containing''. This information will aid staff in locating AACs.
—Remove the column and, thus, the request for information titled:

○ ''Type/s of AAC''

○ ''Type of costs that were passed through the AAC—if fuel, state fuel type''

There has been an increasing number of AAC-related cost types. This field makes it difficult for Commission staff to repopulate the dropdowns for this column without additional OMB approval. The information otherwise gained from respondents supplying the information collected in these columns will not be lost. Staff will locate and

[1] Enacted November 8, 1978

[2] The review requirement is set forth in two paragraphs of Section 208 of PURPA, 49 Stat. 851; 16 U.S.C. 824d.

recover the information from Commission rate filings by using the AAC identification information given by respondents in the first three columns of Question 2.

—Rename Question 2 columns as follows to correct typographical errors:

From	To
Identify service agreement within rate schedule containing AAC	Identify service schedule, if any, where the AAC is located within the rate schedule.
If rate schedule superseded or abandoned during 2012–2013	Was rate schedule superseded or abandoned during 2012–2013?

Additional changes to Question 2 table:

—Add a check box to enable the utility to indicate that it had no non-transmission related AACs during the reporting years, if the situation applies. This box, when checked, clearly indicates that there were no AACs to report.

—Add a ''Copy Row'' button to facilitate data entry.

We are further reducing the amount of information required for AACs that are not fuel adjustment clauses. Utilities with no fuel adjustment clauses only need to respond to questions 1 and 2. Utilities with a FAC will continue to complete the entire form.

Question 3

—Reword the question from:

From	To
If during the 2010 and 2011 period, the Utility had any contracts or agreements for the purchase of either energy or capacity under which all or any portion of the purchase costs were passed through the AAC, for each purchase provide the information requested in the table below. Provide the information separately for each reporting year 2010 and 2011. Do not report purchased power where none of the costs were recovered through an AAC.	If during the 2012–2013 period, the Utility had any contracts or agreements for the purchase of either energy or capacity under which all or any portion of the purchase costs were passed through a fuel adjustment clause (FAC), for each purchase from a PURPA Qualifying Facility (QF) or Independent Power Producer (IPP) provide the information requested in the non-shaded columns of the table below. Provide the information separately for each reporting year 2012 and 2013. Do not report purchased power where none of the costs were recovered through an FAC. For each purchase where costs were flowed through an FAC, fill-in the non-shaded columns and either ''Only energy charges'' or ''The total cost of the purchase of economic power'' columns, whichever apply.

The Commission is only interested in QF and IPP information here and not every power purchase contracts/agreement. The language will be similar to what was used in Form No. 580 interrogatories prior to 2010.

—Remove the request for information and thus the columns titled:

○ Was an after-the-fact comparison made of actual avoided costs against the purchase costs?

○ Were purchases made on an hourly economic dispatch basis?

From the information provided in the 2010 and 2012 filings the Commission has found that it can fully evaluate regulatory compliance without this information.

Question 6

Change the question as follows:

From	To
For each fuel supply contract, where costs were subject to 18 CFR 35.14, (including informal agreements with *associated companies*), in force at any time during 2012 and/or 2013, of longer than one year in duration, provide the requested information. Report the data individually, for each contract, for each calendar year. [No response to any part of Question 6 for fuel oil no. 2 is necessary.] Report all fuels consumed for electric power generation and thermal energy associated with the production of electricity. Information for only coal, natural gas, and oil should be reported. Information for ALL FUELS e.g. fossil fuels, wood chips), EXCEPT URANIUM, should be reported.	For each fuel supply contract, of longer than one year in duration, in force at any time during 2012 and/or 2013, where costs were subject to 18 CFR 35.14, (including informal agreements with *associated companies*), provide the requested information. Report the data individually for each contract for each calendar year. No response to any part of Question 6 for fuel oil no. 2 is necessary. Report all fuels consumed for electric power generation and thermal energy associated with the production of electricity. Information for only coal, natural gas, and oil should be reported.

—As with the request for transportation information that was eliminated in 2010, the Commission has found alternative information sources and analytical approaches sufficient to eliminate the request for fuels other than coal, natural gas and oil.

—Add a ''Copy Contract'' button.

Question 6a

—Add a column labeled ''Is contract evergreen?''.

—Add a column labeled ''Pipeline quality? (Y/N)''.

Question 6b

—Add a new column to the fuel quantity section labeled: ''Coal ($x10^3$tons) not delivered by end of contract year.''

—Add a column labeled ''Pipeline quality? (Y/N)''.

Questions 7 and 8. There are no proposed changes.

Glossary: Define Evergreen contracts as follows: Evergreen contract: a contract that is renewed automatically or by notice from year to year until canceled by either party.

Access to the Revised Materials: A copy of the form, desk reference, and glossary are attached to this docket, but they are not included in the **Federal**

Register.[3] Interested parties can see the form electronically as part of this notice in FERC's eLibrary (*http://www.ferc.gov/docs-filing/elibrary.asp*) by searching Docket No. IC13–13–000. Interested parties may also request paper or electronic copies of the form and desk reference by contacting Ellen Brown, by telephone at (202) 502–8663, by fax at (202) 273–0873, or by email at *DataClearance@ferc.gov.*

Type of Respondents: Large FERC-jurisdictional electric public utilities.

Estimate of Annual Burden:[4] The Commission estimates the total Public Reporting Burden for this information collection as:

FERC FORM NO. 580 (IC13–13–000): INTERROGATORY ON FUEL AND ENERGY PURCHASE PRACTICES

	Number of respondents (A)	Number of responses per respondent (B)	Total Number of responses (A) × (B) = (C)	Average burden hours per response (D)	Estimated total annual burden (C) × (D)
Respondents with FACs	*37*	*0.5*	*18.5*	*103*	*1,905.5*
Respondents with AACs, but no FACs	*10*	*0.5*	*5*	*20*	*100*
Respondents with no AACs nor FACs	*35*	*0.5*	*17.5*	*2*	*35*
Total					*2,040.5*

Despite the changes to the Form 580, burden estimates per response for each entity will not change from previously approved amounts. The burden estimate may vary by utility depending on whether the utility has or does not have an automatic adjustment clause and depending on whether or not those utilities with adjustment clauses allow automatic adjustment of fuel cost.

The total estimated annual cost burden to respondents is $142,835. [2040.5 hours * $70/hour[5] = $142,835]

The estimated annual cost of filing the FERC Form 580 per response is $1,742. [$142,835 ÷ 82 responses = $1,742/response]

Comments: The Commission seeks public comment on and subsequent OMB approval of the proposed revised information collection. Also, the Commission invites comments on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: May 2, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–10946 Filed 5–7–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER13–1252–000]

California Power Exchange Corporation; Notice Setting Deadline To File Reply Comments

On April 29, 2013, the California Power Exchange Corporation filed a motion requesting the Commission to set the date by which it may file reply comments in the above-referenced proceeding. Notice is hereby given that the deadline for submitting such reply comments is set as May 10, 2013.

Dated: May 2, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–10950 Filed 5–7–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2520–072]

Great Lakes Hydro America, LLC; Notice of Intent To File License Application, Filing of Pre-Application Document (PAD), Commencement of Pre-Filing Process, and Scoping; Request for Comments on the Pad and Scoping Document, and Identification of Issues and Associated Study Requests

a. *Type of Filing:* Notice of Intent to File License Application for a New License and Commencing Pre-filing Process.

b. *Project No.:* 2520–072.

c. *Dated Filed:* March 1, 2013.

d. *Submitted By:* Great Lakes Hydro America, LLC.

e. *Name of Project:* Mattaceunk Hydroelectric Project.

f. *Location:* On the Penobscot River in Aroostook and Penobscot counties, Maine, within the towns of Medway, Woodville, Mattawamkeag, and the unorganized township of Molunkus. No federal lands are located within the project boundary.

g. *Filed Pursuant to:* 18 CFR Part 5 of the Commission's Regulations.

h. *Potential Applicant Contact:* Kevin Bernier, Manager, Licensing & Compliance, Brookfield Renewable Energy Group, New England Regional Operations Center, 1024 Central Street, Millinocket, Maine 04462.

[3] The attached form is for illustrative purposes only and does not include all the interactive features of the actual form. For a copy of the actual form, please contact Ellen Brown as indicated in this notice.

[4] Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, reference 5 CFR 1320.3.

[5] FY2013 Estimated Average Hourly Cost per FERC FTE, including salary + benefits.

i. *FERC Contact:* Rachel McNamara at (202) 502–8340 or email at *rachel.mcnamara@ferc.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item o below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See* 94 FERC ¶ 61,076 (2001).

k. *With this notice, we are initiating informal consultation with:* (a) The U.S. Fish and Wildlife Service and/or NOAA Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR, Part 402 and (b) the State Historic Preservation Officer, as required by section 106, National Historical Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating Great Lakes Hydro America, LLC as the Commission's non-federal representative for carrying out informal consultation, pursuant to section 7 of the Endangered Species Act and section 106 of the National Historic Preservation Act.

m. Great Lakes Hydro America, LLC filed with the Commission a Pre-Application Document (PAD; including a proposed process plan and schedule), pursuant to 18 CFR 5.6 of the Commission's regulations.

n. A copy of the PAD is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site (*http://www.ferc.gov*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCONlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in paragraph h.

Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filing and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

o. With this notice, we are soliciting comments on the PAD and Commission's staff Scoping Document 1 (SD1), as well as study requests. All comments on the PAD and SD1, and study requests should be sent to the address above in paragraph h. In addition, all comments on the PAD and SD1, study requests, requests for cooperating agency status, and all communications to and from Commission staff related to the merits of the potential application must be filed with the Commission. Documents may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and five copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

All filings with the Commission must include on the first page, the project name (Mattaceunk Hydroelectric Project) and number (P–2520–072), and bear the appropriate heading: ''Comments on Pre-Application Document,'' ''Study Requests,'' ''Comments on Scoping Document 1,'' ''Request for Cooperating Agency Status,'' or ''Communications to and from Commission Staff.'' Any individual or entity interested in submitting study requests, commenting on the PAD or SD1, and any agency requesting cooperating status must do so by July 2, 2013.

p. Although our current intent is to prepare an environmental assessment (EA), there is the possibility that an Environmental Impact Statement (EIS) will be required. Nevertheless, this meeting will satisfy the NEPA scoping requirements, irrespective of whether an EA or EIS is issued by the Commission.

Scoping Meetings

Commission staff will hold two scoping meetings in the vicinity of the project at the time and place noted below. The daytime meeting will focus on resource agency, Indian tribes, and non-governmental organization concerns, while the evening meeting is primarily for receiving input from the public. We invite all interested individuals, organizations, and agencies to attend one or both of the meetings, and to assist staff in identifying particular study needs, as well as the scope of environmental issues to be addressed in the environmental document. The times and locations of these meetings are as follows:

Daytime Scoping Meeting

Date: Wednesday, June 5, 2013
Time: 12:30 p.m.
Location: Gateway Inn, 1963 Medway Road, Medway, ME 04460
Phone: (207) 746–3193

Evening Scoping Meeting

Date: Wednesday, June 5, 2013
Time: 7:00 p.m.
Location: Gateway Inn, 1963 Medway Road, Medway, ME 04460
Phone: (207) 746–3193

Scoping Document 1 (SD1), which outlines the subject areas to be addressed in the environmental document, was mailed to the individuals and entities on the Commission's mailing list. Copies of SD1 will be available at the scoping meetings, or may be viewed on the web at *http://www.ferc.gov,* using the ''eLibrary'' link. Follow the directions for accessing information in paragraph n. Based on all oral and written comments, a Scoping Document 2 (SD2) may be issued. SD2 may include a revised process plan and schedule, as well as a list of issues, identified through the scoping process.

Environmental Site Review

The potential applicant and Commission staff will conduct an *Environmental Site Review* of the project on Wednesday, June 5, 2013, starting at 3:30 p.m. All participants should meet at the Gateway Inn, located at 1963 Medway Road, Medway, Maine 04460. All participants are responsible for their own transportation. Anyone with questions about the site visit should contact Mr. Kevin Bernier of Brookfield Renewable Energy Group at *Kevin.Bernier@brookfieldrenewable.com* or phone at (207) 723–4341 on or before May 29, 2013.

Meeting Objectives

At the scoping meetings, staff will: (1) Initiate scoping of the issues; (2) review and discuss existing conditions and resource management objectives; (3) review and discuss existing information and identify preliminary information and study needs; (4) review and discuss the process plan and schedule for pre-filing activity that incorporates the time frames provided for in Part 5 of the Commission's regulations and, to the extent possible, maximizes coordination of federal, state, and tribal permitting and certification processes; and (5) discuss the appropriateness of any

federal or state agency or Indian tribe acting as a cooperating agency for development of an environmental document.

Meeting participants should come prepared to discuss their issues and/or concerns. Please review the PAD in preparation for the scoping meetings. Directions on how to obtain a copy of the PAD and SD1 are included in item n. of this document.

Meeting Procedures

The meetings will be recorded by a stenographer and will be placed in the public records of the project.

Dated: May 1, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–10948 Filed 5–7–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER13–1351–000]

Florida Power Development LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Florida Power Development LLC's application for market-based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability is May 22, 2013.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 2, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–10953 Filed 5–7–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER13–1368–000]

NaturEner Wind Watch, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of NaturEner Wind Watch, LLC's application for market-based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability is May 22, 2013.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 2, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–10954 Filed 5–7–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER13–1347–000]

MeadWestvaco Coated Board, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of MeadWestvaco Coated Board, LLC's application for market-based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability is May 22, 2013.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 2, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–10952 Filed 5–7–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER13–1346–000]

Mesa Wind Power Corporation; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Mesa Wind Power Corporation's application for market-based rate authority, with an accompanying rate schedule, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability is May 22, 2013.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 2, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–10951 Filed 5–7–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EL13–60–000; QF13–402–001]

Otter Creek Solar LLC; Notice of Petition for Enforcement

Take notice that on May 1, 2013, Otter Creek Solar LLC (Otter Creek) filed a Petition for Enforcement, pursuant to section 210(h)(2)(B) of the Public Utility Regulatory Policies Act of 1978 (PURPA), requesting the Federal Energy Regulatory Commission (Commission) to initiate enforcement action against the Vermont Public Service Board (VPSB) to remedy the issuance of a series of orders by the VPSB implementing a feed-in tariff program, called the Substainably Priced Energy Enterprise Development or SPEED Program. Otter Creek argues that the SPEED Program is contrary to the requirements of PURPA and the Commission's regulations and in violation of the Federal Power Act.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the

''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on May 15, 2013.

Dated: May 1, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–10947 Filed 5–7–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP13–254–000]

Columbia Gas Transmission, LLC; Notice of Request Under Blanket Authorization

Take notice that on April 24, 2013, Columbia Gas Transmission, LLC (Columbia), 5151 San Felipe, Suite 2500, Houston, Texas 77056, filed a prior notice request pursuant to sections 157.205, 157.208, and 157.216(b) of the Commission's regulations under the Natural Gas Act (NGA) for authorization to replace approximately 6.07 miles of bare, coupled, 12-, 16-, and 20-inch diameter pipeline (Line PM–17) located in Pike County, Kentucky. Columbia states that Line PM–17 will be replaced with 10-inch diameter cathodically protected, steel pipeline. Columbia avers that the reduction in the pipeline diameter will have no adverse impact on Columbia's ability to meet operational needs and firm commitments on Line PM–17. Columbia asserts that it does not propose abandonment of any service in relation to this project. Columbia estimates the cost of the proposed replacement to be approximately $20.2 million, all as more fully set forth in the application, which is on file with the Commission and open to public inspection. The filing may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY, (202) 502–8659.

Any questions regarding the application should be directed to Fredric J. George, Senior Counsel, Columbia Gas Transmission, LLC, PO Box 1273, Charleston, West Virginia 25325–1273, by telephone at (304) 357–2359, or by facsimile at (304) 357–3206.

Any person may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention. Any person filing to intervene or the Commission's staff may, pursuant to section 157.205 of the Commission's regulations under the NGA (18 CFR 157.205) file a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the internet in lieu of paper. See 18 CFR 385.2001(a)(1) (iii) and the instructions on the Commission's Web site (*www.ferc.gov*) under the ''e-Filing'' link. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy regulatory Commission, 888 First Street NE., Washington, DC 20426.

Dated: May 2, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–10949 Filed 5–7–13; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9531–2]

Agency Information Collection Activities OMB Responses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This document announces the Office of Management and Budget (OMB) responses to Agency Clearance requests, in compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et. Seq.). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

FOR FURTHER INFORMATION CONTACT: Rick Westlund (202) 566–1682, or email at *westlund.rick@epa.gov* and please refer to the appropriate EPA Information Collection Request (ICR) Number.

SUPPLEMENTARY INFORMATION:

OMB Responses to Agency Clearance Requests

OMB approvals

EPA ICR Number 1893.06; Emission Guidelines and Compliance Times for Municipal Solid Waste Landfills; 40 CFR part 60 subparts A and Cc; 40 CFR part 62 subpart GGG; was approved on 04/10/2013; OMB Number 2060–0430; expires on 04/30/2016; Approved without change.

EPA ICR Number 1573.13; Part B Permit Application, Permit Modifications and Special Permits (Renewal); 40 CFR parts 264 and 270; was approved on 04/10/2013; OMB Number 2050–0009; expires on 04/30/2016; Approved without change.

EPA ICR Number 1060.16; NSPS for Steel Plants: Electric Arc Furnaces and Argon-Oxygen Decarburization Vessels; 40 CFR part 60 subparts A, AA and AAa; was approved on 04/10/2013; OMB Number 2060–0038; expires on 04/30/2016; Approved without change.

EPA ICR Number 2050.05; NESHAP for Taconite Iron Ore Processing; 40 CFR part 63 subparts A and RRRRR; was approved on 04/10/2013; OMB Number 2060–0538; expires on 04/30/2016; Approved without change.

EPA ICR Number 1415.10; NESHAP for Perchlorethylene Dry Cleaning Facilities; 40 CFR part 63 subparts A and M; was approved on 04/12/2013; OMB Number 2060–0234; expires on 04/30/2016; Approved without change.

EPA ICR Number 1788.11; NESHAP for Oil and Natural Gas Production; 40 CFR part 63, subparts A and HH; was approved on 04/12/2013; OMB Number 2060–0417; expires on 06/30/2013; Approved without change.

EPA ICR Number 1487.12; Consolidated Superfund Information Collection Request (Renewal); 40 CFR part 35, subpart O; 40 CFR part 300, Appendix A; and 40 CFR 300.425, 300.430 and 300.435; was approved on 04/12/2013; OMB Number 2050–0179; expires on 04/30/2016; Approved without change.

EPA ICR Number 1572.10; Hazardous Waste Specific Unit Requirements and Special Waste Processes and

Types (Renewal); 40 CFR 264.11, 264.19, 264.28, 264.57, 264.113(e), 264.191, 264.192(g), 264.193(i), 264.196, 264.197(b), 264.222(b), 264.223(b) and (c), 264.226(c), 264.226(d), 264.227, 264.252(b), 264.253(b) and (c), 264.254, 264.276, 264.278(a)–(f) and (h), 264.278(g), 264.302(b), 264.303(b), 264.304(b) and (c), 264.314, 264.343, 264.347, 264.571, 264.573, 264.574, 264.603, 264.1033(j), 264.1034–264.1036, 264.1061, 264.1062–264.1065, 264.1101, 265.11, 265.19, 265.26, 265.34, 265.44, 265.113(e), 265.191–265.193, 265.196, 265.197(b), 265.221, 265.222, 265.223, 265.225, 265.226, 265.229, 265.254, 265.255, 265.259, 265.276, 265.278, 265.28, 265.301, 265.302, 265.303, 265.304, 265.314, 265.352, 265.383, 265.404, 265.441, 265.443, 265.444, 265.1033–265.1035, 265.1061–265.1064, 265.1101, and 266.70(c); was approved on 04/12/2013; OMB Number 2050–0050; expires on 04/30/2016; Approved with change.

EPA ICR Number 2478.01; Federal Implementation Plan for Oil and Natural Gas Well Production Facilities; Fort Berthold Indian Reservation (Mandan, Hidatsa, and Arikara Nation), North Dakota (Final Rule); 40 CFR 49.4161; was approved on 04/12/2013; OMB Number 2008–0001; expires on 04/30/2016; Approved without change.

EPA ICR Number 2046.07; NESHAP for Mercury Cell Chlor-Alkali Plants; 40 CFR part 63 subparts A and IIIII; was approved on 04/15/2013; OMB Number 2060–0542; expires on 04/30/2016; Approved without change.

EPA ICR Number 2219.04; Tips and Complaints Regarding Environmental Violations (Renewal); was approved on 04/15/2013; OMB Number 2020–0032; expires on 04/30/2016; Approved without change.

EPA ICR Number 2240.04; NESHAP for Area Sources: Polyvinyl Chloride and Copolymer Production, Primary Copper Smelting, Secondary Copper Smelting, and Primary Nonferrous Metals—Zinc, Cadmium, and Beryllium (Renewal); 40 CFR part 63 subparts A, DDDDDD, EEEEEE, FFFFFF and GGGGGG; was approved on 04/15/2013; OMB Number 2060–0596; expires on 04/30/2016; Approved without change.

EPA ICR Number 2354.03; NESHAP for Prepared Feeds Manufacturing; 40 CFR part 63 subparts A and DDDDDDD; was approved on 04/15/2013; OMB Number 2060–0635; expires on 04/30/2016; Approved without change.

EPA ICR Number 2014.05; Reporting and Recordkeeping Requirements of the HCFC Allowance System (Renewal); 40 CFR part 82 subpart A; was approved on 04/18/2013; OMB Number 2060–0498; expires on 04/30/2016; Approved without change.

EPA ICR Number 1797.06; NSPS for Standards of Performance for Storage Vessels for Petroleum Liquids for which Construction, Reconstruction or Modification Commenced after June 11, 1973, and prior to May 19, 1978 (Renewal); 40 CFR part 60 subparts A and K; was approved on 04/19/2013; OMB Number 2060–0442; expires on 04/30/2016; Approved without change.

EPA ICR Number 2098.06; NESHAP for Primary Magnesium Refining; 40 CFR part 63 subparts A and TTTTT; was approved on 04/19/2013; OMB Number 2060–0536; expires on 04/30/2016; Approved without change.

EPA ICR Number 2356.03; NESHAP for Chemical Preparations Industry; 40 CFR part 63 subparts A and BBBBBBB; was approved on 04/19/2013; OMB Number 2060–0636; expires on 04/30/2016; Approved without change.

EPA ICR Number 1739.07; NESHAP for the Printing and Publishing Industry; 40 CFR part 63 subparts A and KK; was approved on 04/19/2013; OMB Number 2060–0335; expires on 04/30/2016; Approved without change.

Withdrawn and Continue

EPA ICR Number 1487.11; Consolidated Superfund Information Collection Request (Renewal); Withdrawn from OMB on 04/10/2013 EPA ICR Number 2434.15; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (New); Withdrawn from OMB on 04/30/2013

John Moses,

Director, Collections Strategies Division.

[FR Doc. 2013–10883 Filed 5–7–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2013–0282; FRL–9810–6]

Proposed Information Collection Request; Comment Request; Willingness To Pay Survey for Santa Cruz River Management Options in Southern Arizona

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit an information collection request (ICR), ''Willingness To Pay Survey for Santa Cruz River Management Options in Southern Arizona'' (EPA ICR No. 2484.01, OMB Control No. 2080–NEW) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a request for approval of a new collection. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before July 8, 2013.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–ORD–2013–0282 online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Matthew A. Weber, Environmental Protection Agency, Western Ecology Division, 200 SW. 35th St., Corvallis, OR 97333; telephone number: 541–754–4315; fax number: 541–754–4799; email address: *weber.matthew@epa.gov*.

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov*

or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets*.

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: The USEPA Office of Research and Development is investigating public values for scenarios of change for perennial reaches of the effluent-dominated Santa Cruz River, Arizona. These values will be estimated via a willingness to pay mail survey instrument. There are two effluent-dominated perennial reaches considered in the survey. A ''South'' reach starts at an outfall in Rio Rico, AZ, and flows northward through Tumacácori National Historical Park. A ''North'' reach is fed by two outfalls in northwest Tucson, Arizona, flows northwest through Marana, AZ. For each of the South and North reaches, two different scenarios of change are considered. The first is a reduction in flow length, and associated decreases in cottonwood-willow riparian forest, a rare forest type in the region. The second is an increase in water quality to allow full contact recreation, such as submersion, at normal flow levels. The baseline flow length and forest acreages, as well as the acreages of forest that would be associated with reduced flow lengths, are derived from natural science research. For the survey, a choice experiment framework is used with statistically designed tradeoff questions. Options to maintain flow length and forest, or increase effluent water quality, are posed as increases in a yearly household tax. Each choice question allows a zero cost ''opt out'' option. The choice experiment is designed to allow isolation of the public value of each marginal change for each reach. A few additional questions to further understand respondent choice motivations, as well as their river-related recreation behavior, are also included. Several pages of background introduce the issue to respondents. A small number of sociodemographic questions are included to gauge how well the sample respondents represent the target population. Samples of the two major metropolitan areas in southern Arizona, Phoenix and Tucson, will receive the survey. The primary reason for the survey is public value research. The Santa Cruz River is a case study of a waterway highly impacted by human modifications. However it still represents potentially valuable ecological commodities such as rare riparian habitat and recreational opportunities for the regional population. The survey results may also be informative to local decision-makers considering Santa Cruz River management options. Water scarcity in the region raises periodic debates on the best uses of effluent. All survey responses will be kept confidential.

Form Numbers: None.

Respondents/affected entities: The target respondents for this survey are representatives 18 yrs or older of households in the two most populated urban areas of Arizona, the Phoenix metro area, and the Tucson metro area. A sample of household representatives 18 yrs or older in each metro area will be contacted by mail following multiple contact protocol in Dillman (2009). A response rate of 30% will be targeted. To increase response rates from the sample, several contacts will be used, including a prenotice to all recipients, a reminder postcard, and followup mailing as needed.

Respondent's obligation to respond: Voluntary.

Estimated number of respondents: The target responses from the Phoenix and Tucson metro areas is 250 households each, or 500 households total.

Frequency of response: One-time response.

Total estimated burden: For a typical respondent, a conservative estimate of their time to review and respond to survey questions is 30 minutes. Assuming the target of 500 people total respond to the survey, the burden is 250 hours.

Total estimated cost: The Bureau of Labor Statistics reports average wage rates for some metropolitan areas, with the most recent data being May 2011 (Bureau of Labor Statistics, 2011). The average hourly wage for all occupations in the Phoenix metro area was $21.61, or an average cost per participant of $10.81. The average hourly wage for all occupations in the Tucson metro area was $20.55, or an average cost per participant of $10.28. Assuming 250 participants in each metro area fill out the survey, the total estimated respondent labor cost is $5,270. This would be a one-time expenditure of their time.

Changes in Estimates: This is the first notice, there is no change in estimates at this time.

Dated: April 19, 2013.

Thomas Fontaine III,

Western Ecology Division Director.

[FR Doc. 2013–10932 Filed 5–7–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2012–0658; FRL–9530–9]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; NSPS/NESHAP for Wool Fiberglass Insulation Manufacturing Plants (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR which is abstracted below describes the nature of the collection and the estimated burden and cost.

DATES: Additional comments may be submitted on or before June 7, 2013.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OECA–2012–0658, to: (1) EPA online, using *www.regulations.gov* (our preferred method), or by email to: *docket.oeca@epa.gov,* or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Enforcement and Compliance Docket and Information

Center, mail code 28221T, 1200 Pennsylvania Avenue NW., Washington, DC 20460; and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Learia Williams, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (202) 564–4113; fax number: (202) 564–0050; email address: *williams.learia@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On October 17, 2012 (77 FR 63813), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to both EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under docket ID number EPA–HQ–OECA–2012–0658, which is available for either public viewing online at *http://www.regulations.gov,* or in person viewing at the Enforcement and Compliance Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue NW., Washington, DC. The EPA Docket Center 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 Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket is (202) 566–1752.

Use EPA's electronic docket and comment system at *http://www.regulations.gov* to either submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov* as EPA receives them and without change, unless the comment contains copyrighted material, Confidentiality of Business Information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *www.regulations.gov.*

Title: NSPS/NESHAP for Wool Fiberglass Insulation Manufacturing Plants (Renewal).

ICR Numbers: EPA ICR Number 1160.12, OMB Control Number 2060–0114.

ICR Status: This ICR is scheduled to expire on June 30, 2013. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB.

Abstract: The affected entities are subject to the General Provisions of the NSPS/NESHAP at 40 CFR part 60, subpart A and part 63, subpart A, and any changes, or additions to the Provisions specified at 40 CFR part 60, subpart PPP and part 63, subpart NNN.

Owners or operators of the affected facilities must submit an initial notification report, performance tests, and periodic reports and results. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. Reports are required annually at a minimum.

Respondents/Affected Entities: Owners or operators of wool fiberglass manufacturing facilities.

Estimated Number of Respondents: 61

Frequency of Response: Occasionally and semiannually

Estimated Total Annual Hour Burden: 18,559

Estimated Total Annual Cost: $2,285,560, which includes $1,797,060 in labor costs, no capital/startup costs, and $488,500 in operation and maintenance (O&M) costs.

Changes in the Estimates: There is no change in the labor hours in this ICR compared to the pervious ICR. This is due to two considerations: (1) The regulations have not changed over the past three years; and (2) the growth rate for the industry is very low, negative or non-existent, so there is no significant change in the overall burden. However, there is an adjustment increase in the total estimated labor costs. The change in cost estimates occurred because the labor rates have increased since the last ICR. This ICR used the most recent labor rates in calculating all burden costs.

Additionally, the annual public reporting and recordkeeping burden for this collection of information has increased from 103 hours per response to 145 hours per response (41 hours per response for 40 CFR part 60, subpart PPP, and 249 hours per response for 40 CFR part 63, subpart NNN). This is due to a correction in the total number of annual responses. The total number of annual responses decreased from 180 to 128. To calculate the number of responses, the previous ICR assumed that all 29 sources subject to subpart NNN were required to submit Startup, Shutdown, and Malfunction (SSM) reports semiannually. This method was inconsistent with the burden calculations for Tables 1a and 1b, which assumed only 10% of all sources submit such reports. This ICR corrected the number of sources for submitting SSM reports, which results in a decrease in the number of responses for subpart NNN.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2013–10885 Filed 5–7–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2003–0073; FRL–9530–6]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Distribution of Offsite Consequence Analysis Information Under the Clean Air Act (CAA) (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), Distribution of Offsite Consequence Analysis Information under Section 112(r)(7)(H) of the Clean Air Act (CAA) (Renewal) (EPA ICR No. 1981.05, OMB Control No. 2050–0172) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through June 30, 2013. Public comments were previously requested via the **Federal Register** (78 FR 2992) on January 15, 2013 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before June 7, 2013.

ADDRESSES: Submit your comments, referencing Docket ID Number, EPA–HQ–OAR–2003-0073 to (1) EPA online using *www.regulations.gov* (our preferred method), by email to *a-and-r-docket@epa.gov*, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov*. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Sicy Jacob, Office of Emergency Management, Mail Code 5104A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–8019; fax number: (202) 564–2620; email address: *jacob.sicy@epa.gov*.

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets*.

Abstract: The Clean Air Act (CAA) section 112(r)(7) required EPA to promulgate reasonable regulations and appropriate guidance to provide for the prevention and detection of accidental releases and for responses to such releases. The regulations include requirements for submittal of a risk management plan (RMP) to EPA. The RMP includes information on offsite consequence analyses (OCA) as well as other elements of the risk management program.

The Chemical Safety Information, Site Security, and Fuels Regulatory Relief Act (CSISSFRRA) required the President to promulgate regulations on the distribution of OCA information (CAA section 112(r)(7)(H)(ii)). The state and local agencies who decide to obtain OCA information must send a written request on their official letterhead to EPA certifying that they are covered persons under Public Law 106–40, and that they will use the information for official use only. EPA will then provide OCA data to those agencies as requested. The rule authorizes and encourages state and local agencies to set up reading rooms. The local reading rooms provide read-only access to OCA information for all the sources in the Local Emergency Planning Committee's (LEPC) jurisdiction and for any source where the vulnerable zone extends into the LEPC's jurisdiction.

Form Numbers: None.

Respondents/affected entities: States, local agencies and members of the public.

Respondent's obligation to respond: Voluntary.

Estimated number of respondents: 865.

Frequency of response: Annual, On Occasion.

Total estimated burden: 1,515 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $48,919 per year, includes $65 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is a decrease of 7,815 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. There has been a decrease in the number of people visiting the reading rooms to obtain OCA data, therefore decreasing the burden on respondents to provide the data.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2013–10886 Filed 5–7–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2012–0657; FRL–9530–7]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; NSPS for Flexible Vinyl and Urethane Coating and Printing (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR which is abstracted below describes the nature of the collection and the estimated burden and cost.

DATES: Additional comments may be submitted on or before June 7, 2013.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OECA–2012–0657, to: (1) EPA online, using *www.regulations.gov* (our preferred method), or by email to: *docket.oeca@epa.gov,* or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, mail code 28221T, 1200 Pennsylvania Avenue NW., Washington, DC 20460; and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Learia Williams, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (202) 564–4113; fax number: (202) 564–0050; email address: *williams.learia@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On October 17, 2012 (77 FR 63813), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to both EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under docket ID number EPA–HQ–OECA–2012–0657, which is available for either public viewing online at *http://www.regulations.gov,* or in person viewing at the Enforcement and Compliance Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue NW., Washington, DC. The EPA Docket Center 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 Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket is (202) 566–1752.

Use EPA's electronic docket and comment system at *http://www.regulations.gov* to either submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in

the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov* as EPA receives them and without change, unless the comment contains copyrighted material, Confidentiality of Business Information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *http://www.regulations.gov.*

Title: NSPS for Flexible Vinyl and Urethane Coating and Printing (Renewal).

ICR Numbers: EPA ICR Number 1157.10, OMB Control Number 2060–0073.

ICR Status: This ICR is scheduled to expire on June 30, 2013. Under OMB regulations, the Agency may continue to either conduct or sponsor the collection of information while this submission is pending at OMB.

Abstract: The affected entities are subject to the General Provisions of the NSPS at 40 CFR part 60, subpart A, and any changes, or additions to the Provisions specified at 40 CFR part 60, subpart FFF. Owners or operators of the affected facilities must submit initial notification, performance tests, and periodic reports and results. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. Reports are required semiannually at a minimum.

Respondents/Affected Entities: Entities potentially affected by this action are the owners or operators of flexible vinyl and urethane coating and printing operations facilities.

Estimated Number of Respondents: 24

Frequency of Response: Initially and semiannually

Estimated Total Annual Hour Burden: 775. Burden is defined at 5 CFR 1320.3(b).

Estimated Total Annual Cost: $297,664, which includes $75,064 in labor costs, $6,600 in capital/startup costs, and $216,000 in operation and maintenance (O&M) costs.

Changes in the Estimates: There is an overall increase in burden primarily due to an increase in the number of sources subject to the standard. There is also a corresponding increase in the total O&M costs because more sources are now subject to the standard. There are additional changes in both respondent and Agency burden estimates that are attributed to the correction of mathematical discrepancies identified in the previous ICR.

John Moses,

Director, Collection Strategies Division.

[FR Doc. 2013–10884 Filed 5–7–13; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[ET Docket No. 13–101; DA 13–801]

Technological Advisory Council Recommendation for Improving Receiver Performance

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: The FCC's Technological Advisory Council (TAC) has been tasked to study the role of receivers in ensuring the efficient use of spectrum and to provide recommendations on avoiding obstacles posed by receiver performance to making spectrum available for new services. Acting on this request, the TAC working group on Receivers and Spectrum provided actionable recommendations to the Chairman at the TAC's December 2012 meeting and has recently formalized these recommendations in a white paper for the Commission. The FCC's Office of Engineering and Technology (OET) invites comment on the TAC white paper and its recommendations to help determine what next steps may be appropriate.

DATES: Comments must be filed on or before June 21, 2013, and reply comments must be filed on or before July 8, 2013.

ADDRESSES: You may submit comments, identified by ET Docket No. 13–101, by any of the following methods:

▪ *Federal Communications Commission's Web site: http://fjallfoss.fcc.gov/ecfs2/.* Follow the instructions for submitting comments.

▪ *Mail:* Robert Pavlak, Office of Engineering and Technology, Electromagnetic Compatibility Division, Room 6–A420, Federal Communications Commission, 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 detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Robert Pavlak, Office of Engineering and Technology, (202) 418–0761, email *Robert.Pavlak@fcc.gov,* or Ronald Repasi, (202) 418–0768, TTY (202) 418–2989.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Public Notice,* ET Docket No. 13–101, DA 13–801, released April 22, 2013. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257), 445 12th Street SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room, CY–B402, Washington, DC 20554. The full text may also be downloaded at: *www.fcc.gov.*

Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

▪ *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://fjallfoss.fcc.gov/ecfs2/.*

▪ *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

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, 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. 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: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

Summary of the Public Notice

1. Early in 2012, Chairman Julius Genachowski tasked the FCC's Technological Advisory Council (TAC) to study the role of receivers in ensuring the efficient use of spectrum and to provide recommendations on avoiding obstacles posed by receiver performance to making spectrum available for new services. Acting on this request, the TAC working group on Receivers and Spectrum provided actionable recommendations to the Chairman at the TAC's December 2012 meeting and has recently formalized these recommendations in a white paper for the Commission to consider, titled, *Interference Limits Policy—The use of harm claim thresholds to improve the interference tolerance of wireless systems;* at *http://transition.fcc.gov/bureaus/oet/tac/tacdocs/WhitePaperTACInterferenceLimitsv1.0.pdf* (TAC white paper). The FCC's Office of Engineering and Technology (OET) invites comment on the TAC white paper and its recommendations to help determine what next steps may be appropriate.

2. In addition to the work of the TAC, the Government Accountability Office (GAO) was tasked by Congress in the Middle Class Tax Relief and Job Creation Act of 2012 to study spectrum efficiency and receiver performance. The GAO report, *Further Consideration of Options to Improve Receiver Performance Needed,* at *http://www.gao.gov/assets/660/652284.pdf*, was recently published and makes reference to the TAC white paper. The report recommends the Commission consider small-scale pilot tests and other methods to collect information on the practical effects of various options for improving receiver performance.

3. Also, in July 2012, the President's Council of Advisors on Science and Technology (PCAST) published a report, titled, *Realizing the Full Potential of Government-Held Spectrum to Spur Economic Growth;* at *http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast_spectrum_report_final_july_20_2012.pdf*. This report noted the important role of receivers in spectrum policy and regulation, and recommended receiver interference limits be defined to specify the level of radio interference that receivers should be expected to tolerate without being able to make claims of harmful interference. The TAC white paper focuses on this definition of ''interference limits'' in making its policy proposals.

4. The TAC white paper sets forth an interference limits policy approach, and suggests that steps should be taken to define the radio environment in which receivers are expected to operate. According to the paper, this approach would make it easier to determine which party bears responsibility for mitigating harmful interference when it occurs, by specifying signal power levels called ''harm claim thresholds'' that a service would be expected to tolerate from other services before a claim of harmful interference could be made. The TAC white paper asserts this approach would avoid the need to mandate that receivers be built, sold, or operated with specific performance characteristics. In addition, it could incentivize incumbent spectrum users to improve receivers to more efficiently use spectrum without stifling innovation and receiver design.

5. OET seeks specific comment on the TAC white paper, which recommends multiple actions the Commission could take to implement an interference limits policy. We also seek comment on the overall interference limits policy approach proposed in that white paper and information on the practical effects of various options including the method used today relative to receiver standards and specifications, the use of multi-stakeholder organizations in the development of interference thresholds, and the role of the FCC.

Interference Limits Policy Approach

6. Comments are requested on the viability of the overall interference limits policy approach presented in the TAC white paper. In particular, we invite parties to comment on the viability of the use of an interference limits policy approach among services operating in adjacent frequency bands. What are the costs and benefits associated with this approach? Are there specific frequency bands or services that would particularly benefit from this approach or where implementation is straightforward and would be appropriate for a trial? We request comment on any areas where additional technical analysis may be needed to implement an interference limits policy approach, such as the impact of various coding and modulation schemes on interference thresholds, propagation models that should be used in determining the interference thresholds, measurement methods for assessing compliance with the limits in cases of interference, and methods for determining the performance characteristics of currently deployed receivers and systems. In addition, we invite parties to discuss the key implementation issues of the proposed approach that would need to be addressed as the Commission focuses on making additional spectrum available for new mobile and fixed wireless broadband services. Would proactive attention to establishing interference limits create more certainty in the marketplace for spectrum (re)allocations?

7. The TAC white paper makes note that an interference limits policy approach may not be appropriate in all cases. Are there other policy approaches that should be considered? Moreover, the GAO report identifies the lack of incentives for manufacturers or spectrum users to incur costs associated with using more robust receivers, and the difficulty of accommodating a changing spectrum environment, such as when spectrum is repurposed for a new use. Are the incentives in the TAC white paper recommendations for improving receiver robustness to interference sufficient? Are there other incentives not mentioned in the TAC white paper recommendations that should be considered? Should the Commission consider circumstances unique to each service, such as the diversity of devices available, the cost of replacement devices, typical replacement times, or sophistication of users that may impact the practicality, necessity, or sufficiency of such an approach? How should the technological evolution of components and receiver design influence the timeframe and evolution of interference limits? In light of these issues, are there other alternatives, or other options within an interference limits policy approach, that should be considered for further analysis and/or small-scale pilot tests? What are the cost and benefit tradeoffs of these alternatives?

Receiver Standards

8. Industry standards for receiver performance exist for certain federal and non-federal wireless services and technologies. There are also wireless services for which there are no industry guidelines or standards for receiver performance. Where industry standards

exist for receivers, what is the relationship between these standards and the method for determining appropriate harm claim thresholds for receivers? How do actual receivers perform in relation to existing performance standards? How are receivers evaluated in meeting those industry standards? Where there are industry standards, how are such standards enforced? To the extent standards are voluntary, how do users of receivers know whether equipment meets or exceeds such standards? Where there are no industry standards for receiver performance, how should acceptable thresholds of receiver performance be developed and validated? What are the technical and performance issues among diverse wireless services that need to be understood and analyzed between different stakeholder groups, especially the developers of wireless transmitters, receivers and components? What are the cost and performance trends of key receiver components that determine practical thresholds of system performance?

9. The TAC recommends that the FCC implement a Web accessible repository (*e.g.,* through the FCC spectrum dashboard) of existing receiver standards, and a voluntary repository of receiver specifications for existing receivers. This, the TAC contends, would facilitate technical information sharing among diverse stakeholder groups of wireless system developers who need to know and understand the specifications of systems other than their own. How effective would this method of information sharing be for product developers? What are the source documents that would be appropriate for such a repository? Are there additional and/or more effective methods, perhaps industry-led, to share receiver technical standards and specifications between stakeholder groups that traditionally do not work together in the same industry groups (*e.g.,* standards organizations)? Given the increasing number of devices developed for international use, would an industry-led approach be more effective than a US-specific repository?

Multi-Stakeholder Organizations

10. The TAC recommends that the Commission encourage the formation of one or more multi-stakeholder groups to investigate interference limits policy at suitable high-value inter-service boundaries. We seek comment on such a multi-stakeholder process and solicit interest from candidate participants. What frequency bands would be most appropriate for considering the formation of a multi-stakeholder organization to develop technical parameters and methods for implementing an interference limits policy? Are there more effective methods of organizing a diverse group of stakeholders for developing such technical parameters?

11. What is the best way to initiate the formation of a multi-stakeholder group? We invite comment and recommendations on applicable governance, issue resolution, and enforcement methods, including but not limited to how stakeholders can coordinate across industry segments, such as those where voluntary standards are needed and/or developed. Also, recognizing that service boundaries and spectrum sharing often involve both non-federal and federal spectrum users, we seek comment on the costs and benefits of a comprehensive approach between the FCC and NTIA to incorporate receiver performance into spectrum management practices. How should the FCC and NTIA coordinate with government agencies and other stakeholders to address situations where large numbers of users are impacted by changes to adjacent spectrum licenses? Should the FCC and NTIA perform band assessments to determine where possible future repurposing in a band might impact adjacent bands and develop plans and processes to ensure proper protections?

Role of the FCC

12. We seek general comment on whether and how the Commission should implement a policy that incentivizes improved interference tolerance of wireless systems. Specifically, should the FCC adopt a policy of employing interference limits in certain cases of neighboring bands and services? Should the FCC adopt specific rules for establishing interference limits that are recommended by one or more multi-stakeholder groups? Should the FCC develop a compliance model similar to the one used in the context of CALEA, in which there is industry-led establishment of standards and solutions and the Commission would get involved only via special petition? We envision that the FCC could be a facilitator in a non-directive role with convening stakeholders. Also, the GAO recommends consideration of small-scale pilot tests of options for improving receiver performance. What should be the scope of an appropriate pilot test? What role should the FCC play in encouraging and initiating industry action? Are there existing FCC proceedings where incentives to improve the interference tolerance of wireless systems should be applied?

Federal Communications Commission.

Julius P. Knapp,

Chief, Office of Engineering and Technology.

[FR Doc. 2013–10840 Filed 5–7–13; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 011325–042.

Title: Westbound Transpacific Stabilization Agreement.

Parties: American President Lines, Ltd./APL Co. Pte Ltd. (withdrawal from agreement effective September 1, 2012); COSCO Container Lines Company Limited; Evergreen Line Joint Service Agreement; Hanjin Shipping Co., Ltd.; Hapag-Lloyd AG; Hyundai Merchant Marine Co. Ltd.; Kawasaki Kisen Kaisha, Ltd.; Nippon Yusen Kaisha Line; Orient Overseas Container Line Limited; and Yangming Marine Transport Corp.

Filing Party: David F. Smith, Esq.; Cozen O'Connor; 627 I Street NW.; Suite 1100; Washington, DC 20006.

Synopsis: This amendment reflects the suspension of the agreement, effective May 1, 2013 through April 14, 2015.

Agreement No.: 011602–013.

Title: Grand Alliance Agreement II.

Parties: Hapag-Lloyd AG; Hapag-Lloyd USA LLC; Nippon Yusen Kaisha; Orient Overseas Container Line, Inc.; Orient Overseas Container Line Limited; and Orient Overseas Container Line (Europe) Limited.

Filing Party: David F. Smith, Esq.; Cozen O'Connor; 1627 I Street NW., Suite 1100; Washington, DC 20006.

Synopsis: The amendment would revise the agreement to reflect the fact that the parties have agreed to charter and rationalize vessel space among themselves and with other VOCCs in the trade pursuant to the parties' participation in the G6 Alliance Agreement.

Agreement No.: 012194–001.

Title: The G6 Alliance Agreement.

Parties: American President Lines, Ltd. and APL Co. Pte, Ltd. (Operating as one Party); Hapag-Lloyd AG; Hyundai Merchant Marine Co., Ltd.; Mitsui O.S.K. Lines, Ltd.; Nippon Yusen Kaisha; and Orient Overseas Container Line, Limited and Orient Overseas Container Line Inc. (Operating as one party).

Filing Party: David F. Smith, Esq.; Cozen O'Connor; 1627 I Street NW., Suite 1100; Washington, DC 20006.

Synopsis: The amendment corrects the name of Orient Overseas Container Line Limited and Orient Overseas Container Line Inc. (Operating as one party).

Agreement No.: 012206.

Title: Industria Armamento Meridionale S.P.A./K-Line Space Charter Agreement.

Parties: Industria Armamento Meridionale S.P.A. (''Inarme'') and Kawasaki Kisen Kaisha, Ltd.

Filing Party: John P. Meade, Esq.; General Counsel; K- Line America, Inc.; 6009 Bethlehem Road; Preston, MD 21655.

Synopsis: The agreement authorizes Inarme to charter space on K-Line vessels in the trade from the United Kingdom to the U.S. East Coast.

Dated: May 3, 2013.

By Order of the Federal Maritime Commission.

Karen V. Gregory,

Secretary.

[FR Doc. 2013–10926 Filed 5–7–13; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 3, 2013.

A. Federal Reserve Bank of Minneapolis (Jacqueline G. King, Community Affairs Officer) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Lake Shore III Corporation,* Glenwood City, Wisconsin; to become a bank holding company by acquiring 100 percent of Hiawatha National Bank, Hager City, Wisconsin.

Board of Governors of the Federal Reserve System, May 3, 2013.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2013–10907 Filed 5–7–13; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Formations of, Acquisitions by, and Mergers of Bank Holding Companies; Correction

This notice corrects a notice (FR Doc. 78–FR 25084) published on pages 25084–25085 of the issue for Monday, April 29, 2013.

Under the Federal Reserve Bank of Kansas City heading, the entry for First Central Nebraska Co, Broken Bow, Nebraska is revised to read as follows:

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Gene R. Giles, Alliance, Nebraska, Sally J. Giles, Denver, Colorado, Randall D. Giles, San Diego, California, Nicholas G. Giles, Lincoln, Nebraska, and Lucas G. Giles,* Lincoln, Nebraska, all of the Giles family group; the Bradley S. Norden Irrevocable Trust and the Brett A. Norden Irrevocable Trust, Brett A. Norden and Bradley S. Norden, as co-trustees of both trusts, all of Highlands Ranch, Colorado, and as members of the Norden family group; Cheryl L. Ryan, the Michael L. Ryan 2011 Irrevocable Trust and the Cheryl L. Ryan 2012 Irrevocable Trust, all of Minden, Nebraska, Jeffrey M. Ryan, Heartwell, Nebraska, and Jamie Johnson, Minden, Nebraska, as co-trustees of both trusts; and Walter D. Wood Revocable Trust, Walter D. Wood, trustee, both of Omaha, Nebraska, as part of the Ryan/Wood family group; to acquire voting shares of First Central Nebraska Co., and thereby indirectly acquire voting shares of Nebraska State Bank and Trust Company, both in Broken Bow, Nebraska.

Comments on this application must be received by May 23, 2012.

Board of Governors of the Federal Reserve System, May 3, 2012.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2013–10922 Filed 5–7–13; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13–0041]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC), Agency for Toxic Substances and Disease Registry (ATSDR) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to ATSDR Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

National Amyotrophic Lateral Sclerosis (ALS) Registry—Revision (0923–0041, Expiration 7/31/13)—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

On October 10, 2008, President Bush signed S. 1382: ALS Registry Act which amended the Public Health Service Act to provide for the establishment of an Amyotrophic Lateral Sclerosis (ALS) Registry. The activities described are part of the effort to create the National ALS Registry. The purpose of the registry is to: (1) Better describe the incidence and prevalence of ALS in the United States; (2) examine appropriate

factors, such as environmental and occupational, that might be associated with the disease; (3) better outline key demographic factors (such as age, race or ethnicity, gender, and family history of individuals who are diagnosed with the disease) associated with the disease; and (4) better examine the connection between ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS. The registry will collect personal health information that may provide a basis for further scientific studies of potentially risks for developing ALS.

After piloting methodology, on October 18, 2010 the Agency for Toxic Substances and Disease Registry (ATSDR) launched the registration component of the National ALS Registry.

The registration portion of the data collection will be limited to information that can be used to identify an individual to assure that there are not duplicate records for an individual. Avoiding duplication of registrants due to obtaining records from multiple sources is imperative to get accurate estimates of incidence and prevalence, as well as accurate information on demographic characteristics of the cases of ALS.

In addition to questions required for registration, there will be a series of short surveys to collect information on such things as military history, occupations, residential history, and family history that would not likely be available from other sources.

This project proposes to add 10 additional risk factor surveys while continuing to collect information on individuals with ALS which can be combined with information obtained from existing sources of information. This combined data will become the National ALS Registry and will be used to provide more accurate estimates of the incidence and prevalence of disease as well as the demographic characteristics of the cases. Information obtained from the surveys will be used to better characterize potential risk factors for ALS which will lead to further in-depth studies.

The existence of the Web site (*http://wwwn.cdc.gov/als*) is being advertised by ATSDR and advocacy groups such as the Amyotrophic Lateral Sclerosis Association (ALSA) and the Muscular Dystrophy Association (MDA). There are no costs to the respondents other than their time. The estimated annualized burden hours are 1,375.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Person with ALS	Validation questions (Screener) for suspected ALS cases	1,670	1	2/60
	Registration Form of ALS cases	1,500	1	7/60
	Cases of ALS completing 1-time surveys	750	16	5/60
	Cases of ALS completing twice yearly surveys	750	2.3	5/60

Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–10853 Filed 5–7–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Administration for Native Americans Tribal Consultation; Notice of Meeting

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice of tribal consultation.

SUMMARY: The Department of Health and Human Services (HHS), Administration for Children and Families (ACF) will host a tribal consultation to consult on ACF programs and tribal priorities.

DATES: July 9–10, 2013.

ADDRESSES: 901 D Street SW., 7th Floor Multipurpose Room, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Lillian A. Sparks, Commissioner, Administration for Native Americans at 202–401–5590, by email at *Lillian.sparks@acf.hhs.gov* or by mail at 370 L'Enfant Promenade SW., 2 West, Washington, DC 20447.

SUPPLEMENTARY INFORMATION: On November 5, 2009, President Obama signed the ''Memorandum for the Heads of Executive Departments and Agencies on Tribal Consultation.'' The President stated that his Administration is committed to regular and meaningful consultation and collaboration with tribal officials in policy decisions that have tribal implications, including, as an initial step, through complete and consistent implementation of Executive Order 13175.

The United States has a unique legal and political relationship with Indian tribal governments, established through and confirmed by the Constitution of the United States, treaties, statutes, executive orders, and judicial decisions. In recognition of that special relationship, pursuant to Executive Order 13175 of November 6, 2000, executive departments and agencies are charged with engaging in regular and meaningful consultation and collaboration with tribal officials in the development of federal policies that have tribal implications, and are responsible for strengthening the government-to-government relationship between the United States and Indian tribes.

HHS has taken its responsibility to comply with Executive Order 13175 very seriously over the past decade, including the initial implementation of a department-wide policy on tribal consultation and coordination in 1997, and through multiple evaluations and revisions of that policy, most recently in 2010. ACF has also developed its own agency-specific consultation policy that complements the department-wide efforts.

ACF's Administration for Native Americans (ANA) will hold a tribal consultation on the morning of July 9, 2013, to discuss the reauthorization of ANA's authorizing legislation, the Native American Programs Act, and the development of data collection elements to collect information on the impact of ACF funding on the members of a tribal community.

A tribal resource day will begin the afternoon of July 9 and the ACF Tribal Consultation Session will begin the morning of July 10 and continue throughout the day until all discussions have been completed. Other ACF

Program Offices that will participate in the consultation include:

- Office of Head Start
- Office of Child Care
- Office of Community Services
- Office of Family Assistance
- Office of Child Support Enforcement
- Administration on Children, Youth and Families:
  - Children's Bureau
  - Family and Youth Services Bureau

To help both you and the ACF principals prepare for this consultation, planning teleconference calls will be held on:

Wednesday, June 5, 2013, 3:00 p.m.—4:00 p.m. (EST).
Wednesday, June 12, 2013, 3:00 p.m.—4:00 p.m. (EST).
Wednesday, June 19, 2013, 3:00 p.m.—4:00 p.m. (EST).

The call-in number and passcode are: 866–763–4038, 354503#.

Testimonies are to be submitted no later than July 2, 2013, to: Lillian Sparks, Commissioner, Administration for Native Americans, 370 L'Enfant Promenade SW., Washington, DC 20447, *anacommissioner@acf.hhs.gov.*

ACF will provide audio and video conferencing of this session for those tribal leaders unable to attend in person. To register for the consultation and obtain information about the audio/video conference, please follow this link: *http://www.regonline.com/tribalconsult2013.*

Dated: April 30, 2013.

George H. Sheldon,

Acting Assistant Secretary for Children and Families.

[FR Doc. 2013–10860 Filed 5–7–13; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Comment Request; State Program Report

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by June 7, 2013.

ADDRESSES: Submit written comments on the collection of information by fax 202.395.5806 or by email to *OIRA_submission@omb.eop.gov,* Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Elena Fazio at 202–357–3583 or email: *elena.fazio@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance.

The Older Americans Act (OAA) requires annual program performance reports from States. In compliance with this OAA provision, ACL developed a State Program Report (SPR) in 1996 as part of its National Aging Program Information System (NAPIS).

The SPR collects information about how State Units on Aging expend their OAA funds as well as funding from other sources for OAA authorized supportive services. The SPR also collects information on the demographic and functional status of the recipients, and is a key source for AoA performance measurement. This collection includes minor revisions of the format from the 2010 approved version. The proposed revised version will be in effect for the FY 2014 reporting year and thereafter, while the current reporting, OMB Approval Number 0985–0008, will be extended to the end of the FY 2013 reporting cycle. The proposed FY 2014 version may be found on the ACL Web site link entitled Proposed SPR for Review available at *http://www.aoa.gov/AoARoot/Program_Results/OAA_Performance.aspx#national* ACL estimates the burden of this collection of information as follows: 2,600 hours.

Dated: May 3, 2013.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2013–10921 Filed 5–7–13; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0093]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request: Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 7, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910-New and title Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Act. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Act—(OMB Control Number 0910-New)

As part of its commitments in PDUFA V. FDA has established a new review Program to promote greater transparency and increased communication between the FDA review team and the applicant on the most innovative products reviewed by the Agency. The Program applies to all New Molecular Entities (NMEs), New Drug Applications (NDAs), and original Biologics License Applications (BLAs) that are received from October 1, 2012, through September 30, 2017. The Program is described in detail in section II.B of the document entitled ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017'' (the ''Commitment Letter'') (available at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf.*

The goals of the Program are to increase the efficiency and effectiveness of the first review cycle and decrease the number of review cycles necessary for approval so that patients have timely access to safe, effective, and high-quality new drugs and biologics. A key aspect of the Program is an interim and final assessment that will evaluate how well the parameters of the Program have achieved the intended goals. The PDUFA V Commitment Letter specifies that the assessments be conducted by an independent contractor and that they include interviews of pharmaceutical manufacturers who submit NMEs, NDAs, and original BLAs to the Program in PDUFA V. The contractor for the assessments of the Program is Eastern Research Group, Inc. (ERG), and the statement of work for the assessments is available at *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM304793.pdf.*

Therefore, in accordance with the PDUFA V Commitment Letter, FDA proposes to have ERG conduct independent interviews of applicants after FDA issues a first-cycle action for applications reviewed under the Program. The purpose of these interviews is to collect feedback from applicants on the success of the Program in increasing review transparency and communication during the review process. ERG will anonymize and aggregate sponsor responses prior to inclusion in the assessments and any presentation materials at public meetings. FDA will publish ERG's assessments (with interview results and findings) in the **Federal Register** for public comment.

In the **Federal Register** of February 19, 2013 (78 FR 11652), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA typically reviews approximately 40 to 45 NMEs, NDAs, and original BLAs per year. ERG will interview one to three sponsor representatives at a time for each application that receives a first-cycle action from FDA up to 135 sponsor representatives per year. Thus, FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest	5	1	5	1.5	7.5
Interviews	135	1	135	1.5	202.5
Total					210

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

ERG will conduct a pretest of the interview protocol with five respondents. FDA estimates that it will take 1.0 to 1.5 hours to complete the pretest, for a total of a maximum of 7.5 hours. We estimate that up to 135 respondents will take part in the post-action interviews each year, with each interview lasting 1.0 to 1.5 hours, for a total of a maximum of 202.5 hours. Thus, the total estimated annual burden is 210 hours. FDA's burden estimate is based on prior experience with similar interviews with the regulated community.

Dated: May 3, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–10898 Filed 5–7–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0559]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Public Health Service Guideline on Infectious Disease Issues on Xenotransplantation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Public Health Service Guideline on Infectious Disease Issues on Xenotransplantation'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *ila.mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On March 20, 2013, the Agency submitted a proposed collection of information entitled ''Public Health Service Guideline on Infectious Disease Issues on Xenotransplantation'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0456. The approval expires on March 31, 2016. A copy of the supporting statement for this information collection is available on

the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–10887 Filed 5–7–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0865]

David Freeman: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring David Freeman for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Freeman was convicted of introducing and delivering for introduction into interstate commerce of a misbranded drug, which relates to the development or approval, including the process for development or approval, of drug products and to the regulation of drug products under the FD&C Act. In addition, FDA determined that the type of conduct that served as the basis for Mr. Freeman's conviction undermines the process for the regulation of drugs. Mr. Freeman was given notice of the proposed debarment and an opportunity to request a hearing within the prescribed timeframe by regulation, but failed to respond. Mr. Freeman's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective May 8, 2013.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if it finds that the individual has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under the FD&C Act, and if FDA finds that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

On May 5, 2010, Mr. Freeman pleaded guilty to a misdemeanor offense of introducing and delivering for introduction into interstate commerce of a misbranded drug in violation of 21 U.S.C. 352(o), 331(a), and 333(a)(1). On July 7, 2011, the U.S. District Court for the District of Nevada entered judgment against Mr. Freeman for the misdemeanor offense of misbranding.

The FDA's finding that debarment is appropriate is based on the misdemeanor conviction referenced herein. The factual basis for the conviction is as follows: On July 23, 2008, Agents from Customs and Border Protection found two express mail packages at JFK International Mail Facility, each with a return address of Muhi Trading Corporation, Bahadur Manzil. A border search was conducted on both packages, which revealed 1,000 capsules labeled as the prescription drug omeprazole in each package. The pills were in blister packs on which was written ''Omega Biotech LTD.'' Mr. Freeman and his co-defendant, Mr. Ashley Brandon Foyle, were the importers of record for the packages. At all relevant times, neither Muhi Trading Corporation nor Omega Biotech LTD. were registered to manufacture, prepare, propagate, compound, or process drugs.

On January 20, 2009, an Agent with the Office of Criminal Investigations at FDA (OCI) conducted an undercover purchase of omeprazole through a Web site Mr. Freeman and Mr. Foyle used to sell their misbranded drugs. Mr. Freeman and Mr. Foyle repackaged omeprazole in their apartment and mailed it to the undercover agent. Laboratory testing of the tablets confirmed that the tablets contained omeprazole. On February 24, 2009, OCI agents searched Mr. Freeman and Mr. Foyle's residence and found unapproved drugs. The omeprazole pills that Mr. Freeman and Mr. Foyle imported, repackaged and sold had not been approved by or registered with FDA. At no time was Mr. Freeman and Mr. Foyle's apartment registered as a location where drugs could be manufactured, prepared, propagated, compounded, or processed.

As a result of his convictions, on October 31, 2012, FDA sent Mr. Freeman a notice by certified mail proposing to debar him for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(b)(2)(B)(i)(I) of the FD&C Act that Mr. Freeman was convicted of a misdemeanor under Federal law for conduct relating to the development or approval, including the process for development or approval, of drug products and to the regulation of drug products under the FD&C Act, and the conduct that served as the basis for Mr. Freeman's conviction undermines the process for the regulation of drugs because the introduction of misbranded drugs into interstate commerce is prohibited by the FD&C Act. The proposal also offered Mr. Freeman an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Freeman failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(b)(2)(B)(i)(I) of the FD&C Act under authority delegated to him (Staff Manual Guide 1410.35), finds that David Freeman has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval, including the process for development or approval, of drug products and relating to the regulation of drug products under the FD&C Act, and that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

As a result of the foregoing finding, Mr. Freeman is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**), (see sections 306(c)(1)(B), (c)(2)(A)(iii), and 201(dd) of the FD&C Act (21 U.S.C. 355a(c)(1)(B), (c)(2)(A)(iii), and 321(dd))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or

contractor, or otherwise uses the services of Mr. Freeman, in any capacity during Mr. Freeman's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 355b(a)(b)). If Mr. Freeman provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Freeman during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Freeman for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2012–N–0865 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 3, 2013.

Melinda K. Plaisier,

Acting Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs.

[FR Doc. 2013–10973 Filed 5–7–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0722]

Guidance for Industry: Implementation of an Acceptable Abbreviated Donor History Questionnaire and Accompanying Materials for Use in Screening Frequent Donors of Blood and Blood Components; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Implementation of an Acceptable Abbreviated Donor History Questionnaire and Accompanying Materials for Use in Screening Frequent Donors of Blood and Blood Components'' dated May 2013. The guidance document recognizes the abbreviated donor history questionnaire and accompanying materials (aDHQ documents), version 1.3 dated December 2012, prepared by the AABB Donor History Task Force, as an acceptable mechanism for collecting blood donor history information from frequent donors of blood and blood components that is consistent with FDA's requirements and recommendations for collecting donor history information. The aDHQ documents will provide blood establishments that collect blood and blood components with a specific process for administering questions to frequent donors of blood and blood components to determine their eligibility to donate. The guidance announced in this notice finalizes the draft guidance of the same title dated October 2011.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Implementation of an Acceptable Abbreviated Donor History Questionnaire and Accompanying Materials for Use in Screening Frequent Donors of Blood and Blood Components'' dated May 2013. The guidance document recognizes the aDHQ documents, version 1.3 dated December 2012, prepared by the AABB Donor History Task Force, as an acceptable mechanism for collecting blood donor history information from frequent donors of blood and blood components that is consistent with FDA's requirements and recommendations. The aDHQ User Brochure defines a frequent donor as a donor who has previously donated two times using the full-length donor history questionnaire, one donation of which occurred within the previous 6 months. The aDHQ documents will provide blood establishments that collect blood and blood components with a specific process for administering questions to frequent donors of blood and blood components to determine their eligibility to donate. The guidance also advises licensed manufacturers who choose to implement the acceptable aDHQ documents on how to report the manufacturing change consisting of the implementation of the aDHQ documents under 21 CFR 601.12.

In the **Federal Register** of October 24, 2011 (76 FR 65735), FDA announced the availability of the draft guidance of the same title dated October 2011. FDA received some comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes: Referencing the most current version of the acceptable aDHQ documents, clarifying that the full-length and abbreviated questionnaires are designed to be implemented together, and editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated October 2011.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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. 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 601.12 and Form FDA 356(h) have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR 640.63 have been approved under OMB control number 0910–0116.

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 guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: May 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–10889 Filed 5–7–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Microbiology 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: Microbiology 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 June 13, 2013, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, C and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900.

Contact Person: Shanika Craig, *Shanika.Craig@fda.hhs.gov,* Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6639, Food and Drug Administration, 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 June 13, 2013, the committee will discuss and make recommendations regarding the possible reclassification of influenza detection devices, currently regulated as class I. The committee's discussion will involve making recommendations regarding regulatory classification to either confirm class I or reclassify these devices into class II with special controls. The committee will address issues such as device performance and public health impact to determine whether special controls are needed to ensure the safety and effectiveness of these tests through their total product life cycle. The proposed special controls will be discussed to support the possible reclassification.

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 June 4, 2013. 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 May 30, 2013. 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 May 31, 2013.

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 AnnMarie Williams, Committee Management Staff, at *annmarie.williams@fda.hhs.gov* or 301–796–5966, 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: May 3, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–10891 Filed 5–7–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0430]

510(k) Device Modifications: Deciding When To Submit a 510(k) for a Change to an Existing Device; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the public meeting entitled ''510(k) Device

Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device.'' The focus of this meeting is FDA's interpretation of its regulations concerning when a modification made to a 510(k)-cleared device requires a new 510(k) submission.

DATES: The meeting will be held on June 13, 2013, from 9 a.m. to 5 p.m. EDT.

ADDRESSES: The meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: For technical information: Michael J. Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 301–796–6283, email: *michael.ryan@fda.hhs.gov.* For registration questions: Joyce Raines, Center for Devices and Radiological Health, Food and Drug Administration, 301–796–5709, email: *joyce.raines@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this meeting must register online by 5 p.m. EDT, May 30, 2013. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the meeting will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Joyce Raines, 301–796–5709 or email: *joyce.raines@fda.hhs.gov* no later than 5 p.m. EDT, May 30, 2013.

To register for the meeting, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this meeting from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Joyce Raines to register (see *Contact Persons*). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Meeting: This meeting will also be available via Webcast. Persons interested in viewing the Webcast must register online by May 30, 2013, 5 p.m. EDT. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after May 31, 2013. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Requests for Oral Presentations: This meeting includes a public comment session and topic-focused sessions. During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topics you wish to address. FDA has identified general topics in this document. FDA will do its best to accommodate requests to make public comments and participate in the focused sessions. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by June 3, 2013. All requests to make oral presentations must be received by the close of registration on May 30, 2013, 5 p.m. EDT. If selected for presentation, all of your presentation materials must be emailed to Michael Ryan (see *Contact Persons*) no later than June 6, 2013. No commercial or promotional material will be permitted to be presented or distributed at the meeting.

Comments: FDA is holding this meeting to obtain information on its interpretation of the 510(k) device modifications regulations, and specifically, deciding when a 510(k) should be submitted for a change to a 510(k)-cleared device. To permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the meeting topics. FDA would like to receive these comments by May 30, 2013, so they can be discussed during the meeting; however, comments related to this meeting will be accepted until July 13, 2013.

Regardless of attendance at the meeting, interested persons may submit written comments regarding this document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, or electronic comments to *http://www.regulations.gov.* It is necessary to send only one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. 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.*

Transcript: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM after submission of a Freedom of Information Act request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcript will also be available approximately 45 days after the meeting on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this meeting from the posted events list.)

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration Safety and Innovation Act (FDASIA) became law on July 9, 2012. FDASIA added section 510(n)(2) to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(n)), which requires FDA to withdraw its 2011 draft guidance, ''Deciding When to Submit a 510(k) for a Change to an Existing Device,'' and states that the 1997 final guidance of the same name shall be in effect until FDA issues a guidance or a regulation on the topic. Section 510(n)

further requires FDA to submit a report not later than 18 months after the enactment of FDASIA to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate on when a new 510(k) should be submitted to FDA for a modification or change to a legally marketed device. Under this provision, the report must address the interpretation of several phrases in 21 CFR 807.81(a)(3) (the regulation governing submission of 510(k)s for changed or modified devices), possible processes for industry to use to determine whether a new 510(k) is required, and how to leverage existing quality system requirements to reduce premarket burden, facilitate continual device improvement, and provide reasonable assurance of safety and effectiveness of modified devices. FDA is holding this public meeting to solicit input on these issues from all interested stakeholders.

II. Topics for Discussion at the Meeting

FDA invites public input on its interpretation of its regulations concerning when a new 510(k) is required for a change to a 510(k)-cleared device. This input will be used to formulate FDA's report to Congress, as well as any future guidance on this topic. FDA would like to solicit comments on the following policy options, both in the form of submissions to the docket for this **Federal Register** notice and in discussion during the public meeting. Please note that implementation of some of these options may require regulatory changes beyond a guidance document.

A. Risk Management

Industry members have proposed use of risk management in the decision process on whether a medical device modification requires a new 510(k) submission. FDA would like to solicit specific, detailed, and practicable proposals that incorporate risk management into this decision process in a way that ensures appropriate and consistent modification decisions by industry and FDA staff. Appropriate decisions in this context are those that allow for both medical device innovation and effective FDA oversight of device changes. Consistent results are a key consideration, as these decisions must be made by many different types of medical device companies and by different FDA review divisions. Inconsistent decisions will make policy unclear and unpredictable for those making future decisions. Proposals must ensure consistency of 510(k) modifications policy, and address and resolve the following concerns.

1. Risk Management is a Process—Published risk management standards and guides, such as the International Organization of Standardization's (ISO's) 14971:2007, ''*Medical devices—Application of risk management to medical devices,*'' are not designed to produce a determination on whether a modified device requires a 510(k). How can risk management be tied to a decision on whether a modification requires a new 510(k)? More specifically, how can FDA tie risk management to the decision that a change or modification in a device is one that could significantly affect the safety or effectiveness of the device? Provide examples of different devices and how the suggested tie between risk management and 510(k) modifications would result in consistent decision making.

2. There are Many Different Ways to do Risk Management—FDA's risk analysis process is described in the preamble to 21 CFR part 820, the Quality System Regulation, at 61 FR 52620 (October 7, 1996), in the response to comment 83. Although FDA's risk analysis process is similar to some documented risk management processes, there are many other ways to conduct risk management and still meet FDA requirements. Even ISO 14971, one of the more common risk management guides, allows for flexibility in its processes such that different manufacturers following ISO 14971 could conceivably reach different risk management decisions for similar device changes. How can a single risk management process be chosen that leads to consistent and appropriate decisions on whether a 510(k) is required for a device modification?

3. Risk Management Analyses Inherently Involve Subjectivity—Risk management requires the manufacturer to: (1) Establish ''criteria for risk acceptability, based on the manufacturer's policy for determining acceptable risk,'' (2) predict known and foreseeable hazards associated with the device, (3) estimate the risks for each hazard, and (4) evaluate the risks of each associated hazard using the manufacturer's established criteria. ISO 14971. FDA is not aware of universally accepted risk acceptability criteria for medical devices. Furthermore, it is often difficult to find objective data to help determine frequency and even severity of risk, which often leads to inconsistent risk analyses. How can the inherent subjectivity of risk management be controlled to ensure consistent and appropriate decisions on whether a 510(k) is required for a device modification?

4. A Company's Risk Management Processes are Contained Within its Overall Quality System and May Not be Specifically Scrutinized by FDA During 510(k) Reviews—To consider integration of risk management in the 510(k) modification decision-making process, FDA must have assurance that a company's risk management process is comprehensive and appropriately implemented. How can FDA obtain such assurance?

B. Reliance on Design Control Activities

FDA is soliciting proposals for how industry and FDA could utilize design control activities such as design verification and validation to ensure that device modifications are appropriately evaluated prior to marketing. FDA would need some form of effective oversight in this process to properly perform its function of protecting the public health. The Agency would need the opportunity to review design control activities when necessary because improper application of these activities may lead to incomplete or inaccurate evaluations of design changes and the marketing of unsafe or ineffective devices. At this time, FDA generally reviews design control information for 510(k)-eligible devices only during inspections, and inspections do not necessarily focus on the specific information (such as design specifications, testing protocols, etc.) that FDA needs to review to ensure that design changes are properly evaluated. Inspection resources are also limited. Any proposal for reliance on design control activities as part of FDA's 510(k) modifications policy should consider how FDA may ensure effective oversight. Input on the following specific questions is requested.

1. FDA Does Not Typically Review Design Control Information Prior to Marketing Clearance and Resource Issues, Among Other Things, Limit the Extent of its Review of Design Control Information—How can FDA ensure that design control activities will limit the potential for marketing of device modifications that may be unsafe or ineffective?

2. Although 21 CFR 820.30 Imposes the Same Design Control Requirements on All Medical Device Manufacturers, the Ways in Which Manufacturers Comply with These Requirements Vary—How can FDA ensure consistency in use of design controls to ensure that only safe and effective modified devices are marketed?

C. Critical Specifications

Industry members have proposed the use of critical specifications, a new concept, to make decisions on whether a 510(k) is required for a device modification easier. This concept would be one way that FDA could link use of design control activities to 510(k) modification decisions.

Under this proposal, if FDA and manufacturers can identify essential device specifications—critical specifications—and can agree on limits and testing protocols for those specifications within a 510(k), then a device manufacturer may make modifications to a device, and as long as the resulting device remains within the agreed-upon limits for all of the critical specifications, no new 510(k) would be required for that modified device. This approach could allow FDA to rely on the quality system regulation to ensure that qualifying changes could not significantly affect safety and effectiveness because there was no change to a critical specification. FDA would like to discuss the feasibility of this approach, both for manufacturers and FDA's review staff, and how it might be implemented. It is important to note that this approach would not apply to changes to intended use or labeling, as those aspects of a device are not associated with specifications.

Critical specifications could include a range of technological and material design aspects, such as dimensional specifications, shelf life, or material purity. Critical specifications would necessarily be device specific, so it would be impossible to identify all of the possible specifications in guidance, although FDA guidance could note useful examples. To qualify as a critical specification, FDA and the 510(k) submitter would have to agree on the identity and parameters of a critical specification within a 510(k) review. The manufacturer would have to clearly identify types of changes that might be made, which specifications it would designate as critical for those types of changes, and specification bounds or tolerances. For example, if a manufacturer anticipates possible changes in materials for an implant (e.g., due to supplier changes that may occur post-clearance), then it might wish to designate tensile strength of the material as a critical specification. It would then set parameters for properties that the new material needs to meet; for instance, tensile strength must be 950 MPa ± 15 MPa (megapascals). The 510(k) would also describe how tensile strength would be tested. FDA reviewers would need to consider whether any other properties should be identified as critical specifications for the type of change in question, and whether appropriate test methods have been identified to ensure the modified device will meet its critical specifications. Voluntary consensus standards (such as those recognized on FDA's Web site in its recognized standards database at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm*) could be used to determine critical specifications and their parameters or testing protocols. If critical specifications are agreed on prior to 510(k) clearance, then a manufacturer who modifies its device after clearance would be able to do so without submission of a new 510(k) as long as the agreed-upon verification and validation activities show those critical specifications are unchanged.

To take advantage of this approach, manufacturers would have to identify the following in their 510(k) submissions:

- A list of potential changes that might be made;
- Critical specifications for each change: Those device specifications—physical, material, or performance—that are essential to safe and effective use of the device (e.g., tensile strength);
- Bounds for those specifications that a changed device must remain within (e.g., 950 MPa ± 15 MPa); and
- The verification and validation test protocols that will be used to examine those specifications pre- and post-modification, within the rubric of the quality system regulation.

FDA's review staff would be responsible for reviewing the above information and determining whether a change that results in a device that remains within the identified specifications could significantly affect safety or effectiveness.

FDA is soliciting input on the feasibility of the critical specifications approach and proposals for how FDA could implement such a program. Input on the following specific questions is requested.

1. How could critical specifications be incorporated into FDA's review process? Review of critical specifications proposals in 510(k)s will require additional review time and resources. How should situations where agreement cannot be reached within review timeframes be handled? How could situations where FDA is ready to proceed with a substantial equivalence decision, but critical specifications have not been agreed upon, be handled?

2. How could critical specifications agreements be documented? Should they be summarized in 510(k) Summaries or substantial equivalence letters?

3. Should use of critical specifications be limited to certain types of changes? If so, which ones?

4. Are there particular specifications that could be deemed critical for all devices? If so, which ones?

5. Could critical specifications be implemented as an optional paradigm? This approach could potentially be implemented as an optional approach that manufacturers could use where it is most efficient; manufacturers that chose not to identify critical specifications in a 510(k) would then be subject to the current 510(k) modifications decision-making paradigm. Please discuss the practical implications of this approach.

D. Risk-Based Stratification of Medical Devices for 510(k) Modifications Purposes

FDA is seeking comments on the practicality of stratifying device types that require 510(k)s by risk. Under such a framework, FDA would expect 510(k)s for modifications of higher risk devices that meet the standard in 21 CFR 807.81(a)(3). For lower risk devices, FDA would not expect 510(k)s for all modifications that meet the standard in 807.81(a)(3). However, because modifications to lower risk devices could still result in harm or injury, FDA would expect 510(k)s for certain modifications (for example, changes to the indications for use) even if the device is lower risk. FDA could require some other measure, such as periodic reporting, for modifications of lower risk devices that are not submitted in 510(k)s. This approach would allow FDA to focus review resources on areas that are more important from a public health perspective. Comments on this approach should address the following questions.

1. How should FDA delineate higher versus lower risk devices? For example, would higher risk devices include only those designated as life sustaining, life supporting, or implants?

2. Should FDA require some other measure, such as periodic reports, for modified lower risk devices in lieu of 510(k) submissions?

3. Because modifications to lower risk devices could still result in harm or injury, FDA believes that some modifications to lower risk devices should still be reviewed in 510(k) submissions prior to marketing. How should FDA delineate which lower risk device modifications require 510(k)s and which do not?

E. Periodic Reporting

FDA is soliciting comments on the advisability of requiring periodic reporting for modifications to 510(k)-cleared devices that do not require new 510(k) submissions. FDA does not typically review 510(k) modifications decisions that do not result in 510(k) submissions, unless that information is specifically looked at during an inspection or submitted in conjunction with future changes that do require a 510(k). If manufacturers were required to submit periodic reports identifying and describing their design changes that did not result in 510(k) submissions, FDA would then review these changes and ensure that decisions were made appropriately. This process would likely be similar to annual reporting of device changes for approved class III devices. Over time, periodic reporting would give FDA a more complete picture of the changes industry is making to 510(k)-cleared devices, and may allow FDA to tailor 510(k) modifications requirements to ensure that the Agency is reviewing only the changes it needs to in new 510(k) submissions. Review of periodic reports, however, would require additional FDA resources. Comments on periodic reporting should address the following questions.

1. How often should FDA require periodic reports, e.g., annually, biannually, etc.?
2. Should FDA require periodic reports for all 510(k) devices or only certain devices? If not all devices, then which ones?
3. What information should be included in a periodic report?

F. Other Policy Proposals

FDA acknowledges that any one of the above options may be insufficient on its own; if any changes are made to FDA's 510(k) modification policy, the Agency may adopt a combination of those options. FDA also acknowledges that other options may exist that have not been identified above. FDA is therefore soliciting any other proposals for revising the Agency's 510(k) modification policy. Any policy must ensure:

- Consistent decision-making by both industry and FDA;
- Adequate control of device modifications that could significantly affect safety or effectiveness; and
- Effective FDA oversight of modifications to 510(k)-cleared devices to adequately protect the public health and allow for medical device innovation.

Proposals should be as detailed and specific as possible, and should take into account the issues discussed above in the individual options.

G. Examples

In addition to the options discussed above, FDA is seeking specific examples of device changes that manufacturers have made that should not trigger the requirement for a new 510(k) submission, with explanations as to why 510(k) submissions should not be required. These examples will help FDA develop an appropriate 510(k) modifications policy. FDA typically sees only those device modifications that result in new 510(k) submissions; device changes that do not result in new 510(k) submissions generally are not reviewed by the Agency. Industry provision of these changes will help inform FDA's 510(k) modifications interpretation.

Examples of device changes may also be used for discussion during this public meeting. All examples discussed publicly will be de-identified. Examples may be submitted to the Agency in de-identified form through third parties such as trade associations.

Dated: May 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–10888 Filed 5–7–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Summary of Responses To Request for Information (RFI): Opportunities To Apply a Department of Health and Human Services Message Library To Advance Understanding About Toddler and Preschool Nutrition and Physical Activity

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Summary of Responses to Request for Information (RFI).

SUMMARY: On January 29, 2013, the Health Resources and Services Administration (HRSA) issued a *Request for Information (RFI)* to solicit ideas and information related to ways in which the U.S. Department of Health and Human Services (HHS) can work with interested partners to disseminate and apply *TXT4Tots,* a library of short, evidence-based messages on nutrition and physical activity targeted to parents, caregivers, and health care providers of children ages 1–5 years. HRSA released the *TXT4Tots library* in English and Spanish on February 19, 2013; and followed with an Open Forum on February 20, 2013, to provide further opportunity for input on dissemination and application of the library of messages. HHS received over 25 written responses to the RFI, and approximately 100 individuals participated in the Open Forum.

Comments and Responses: The written responses to the RFI as well as the comments received through the Open Forum indicate that TXT4Tots aligns with the activities of many existing organizations and programs. Several of the respondents expressed an interest in collaborative opportunities to incorporate the messages into current outreach and educational efforts. Some examples of current programs that could leverage the TXT4Tots messages include initiatives at the federal, state, and local levels. The majority of the suggested organizations and programs focus on promoting healthy choices for children and their families. Recommendations included integrating the TXT4Tots messages into their programs and services or using the internet to disseminate the information through Web sites and social media.

Respondents also emphasized that mobile health, social media, and other innovative strategies are a valuable resource to reach a diverse population and can be effectively leveraged to support equitable access to health information. With regard to vehicles for dissemination of the TXT4Tots messages, respondents suggested that they needn't be complicated, but should be user friendly. In addition, respondents noted that the most effective tools for dissemination are those that can fully engage the end users. Specific suggestions for dissemination of the TXT4Tots messages included social media, existing tools and applications, existing Web sites and web services, and text messages, as well incorporating messages into baby product packaging, curricula, health fairs, emails, newsletters, and print materials. Emphasis was placed on leveraging existing platforms that promote healthy choices for young children and could readily integrate the TXT4Tots message content. Respondents also recommended that the TXT4Tots messages be linked to additional sources of information; for example, if utilized as a text message program, URLs could be included to link the message recipients to Web sites with additional information. In addition, social media posts could link to Web sites with ideas for healthy recipes and age-appropriate activities to compliment the messages.

Some respondents indicated that the use of certain technology-based platforms may restrict access to the underserved, who might have limited access to smartphones or the internet. One additional concern that was voiced by numerous respondents was confusion regarding the purpose of TXT4Tots and how it is intended to be used. Specifically, it was unclear that this is a library of messages that could be used in a variety of existing platforms and products and not exclusively a text messaging service. Guidance regarding specific details about the use of the TXT4Tots messages has been added to the TXT4Tots Web page (*http://www.hrsa.gov/healthit/txt4tots*).

HRSA appreciates all of the thoughtful comments received either via the RFI or Open Forum. Guidance regarding specific details about the use of the TXT4Tots messages has been added to the TXT4Tots Web page (*http://www.hrsa.gov/healthit/txt4tots*). It is our hope that the thoughtful recommendations and comments will spur others to explore innovative ways for disseminating the TXT4Tots content.

FOR FURTHER INFORMATION CONTACT: Bethany Applebaum, MPH, Health Resources and Services Administration, Office of Women's Health and Office of Health Information Technology and Quality, 5600 Fishers Lane, Room 7–100, Rockville, Maryland 20857, or email *bapplebaum@hrsa.gov.*

Dated: May 2, 2013.

Mary K. Wakefield,

Administrator.

[FR Doc. 2013–10968 Filed 5–7–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Induced Pluripotent Stem Cells Generated Using Lentivirus-Based Reprogramming

Description of Technology: Five human induced pluripotent stem cells (iPSC) lines are generated using lentivirus-based reprogramming technology. These lines are pluripotent, meaning they have the potential to differentiate into all cells in the body, and theoretically can proliferate/self-renew indefinitely. The iPSC lines are: NC1 (derived from female's fibroblasts), NC2 (derived from female's fibroblasts), NC3 (derived from male's HUVECS), NC4 (derived from male's fibroblasts) and NC5 (derived from female's fibroblasts). Further details of these cells are available upon request. NC1 uses a retrovirus delivery system incorporating the following vectors: pMIG–hKLF4, pMIG–hOCT4, pMIG–hSOX2, and MSCV h c–MYC IRES GFP. NC2–NC5 use the hSTEMCCA–loxP lentivirus delivery system (a gift from Dr. Gustavo Mostoslavsky). These cell lines will be useful for studies related to stem cell biology, understanding diseases, potential cell therapies, and small molecule screening.

Potential Commercial Applications: The iPSCs of this technology are useful:

(a) To study the biology of stem cell development,

(b) as controls in studies to screen for small molecules to change cell fate and/or to alleviate the phenotypes of various diseases, and

(c) to test different characterization and differentiation assays.

Competitive Advantages:

- These cells can serve as control cells and, thus, significantly reduce the cost of initiating many research projects.
- These cells can be a good source of control cells.

Development Stage:

- Prototype
- Pilot
- Early-stage
- In vitro data available

Inventors: Drs. Guibin Chen and Manfred Boehm (NHLBI)

Intellectual Property: HHS Reference No. E–274–2012/0—Research Tools. Patent protection is not being pursued for this technology.

Licensing Contact: Suryanarayana (Sury) Vepa, Ph.D., J.D.; 301–435–5020; *vepas@mail.nih.gov.*

Collaborative Research Opportunity: The National Heart, Lung, and Blood Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Induced Pluripotent Stem Cells. For collaboration opportunities, please contact Denise Crooks, OTTAD, at 301–435–0103.

Stapled Peptides for Treatment of Cardiovascular Diseases and Inflammation

Description of Technology: The invention is directed to small molecule mimetics of apolipoproteins that have an inter-helical hydrocarbon bond, which stabilizes helix formation.

Apolipoproteins facilitate the transport of lipids and cholesterol in the body. Mimetics of apolipoproteins have been used to treat cholesterol-related disorders. However, these mimetics are susceptible to degradation in biological fluids and as a result, their ability to bind cholesterol becomes diminished over time.

Scientists at NHLBI have devised methods to stabilize and improve the performance of apolipoprotein mimetic peptides, using a modified hydrocarbon chain (''stapled apolipoproteins''). These stapled apolipoproteins are superior to singular apolipoproteins in that they are more resistant to enzymatic degradation and efflux a greater amount of cellular cholesterol.

Stapled apolipoproteins can be used in the treatment of cardiovascular diseases, particularly for treatment of atherosclerosis.

Potential Commercial Applications:

- Treatment of inflammation and cardiovascular diseases, including hyperlipidemia, atherosclerosis, restenosis, and acute coronary syndrome.
- Inclusion in oral, intravenous or transdermal peptide formulations.

Competitive Advantages:

- Stapled apolipoproteins are more resistant to proteolysis and display enhanced bioavailability.
- Stapled apolipoproteins are amenable to oral delivery and have increased permeability to the blood brain barrier.

Development Stage:

- Pre-clinical
- In vitro data available
- In vivo data available (animal)

Inventors: Alan T. Remaley (CC), Marcelo A. Amar (NHLBI), Imoh Z.

Ikpot (NHLBI), Denis O. Sviridov (NHLBI), David O. Osei-Hwedieh (NHLBI), Scott Turner (KineMed)

Publication: Osei-Hwedieh DO, et al. Apolipoprotein mimetic peptides: Mechanisms of action as anti-atherogenic agents. Pharmacol Ther. 2011 Apr;130(1):83–91. [PMID 21172387]

Intellectual Property: HHS Reference No. E–126–2011/0—US Application No. 61/480,986 filed 29 April 2011; PCT Application No. PCT/US1235870 filed 30 April 2012

Licensing Contact: Lauren Nguyen-Antczak, Ph.D., J.D.; 301–435–4074; *lauren.nguyen-antczak@nih.gov*

Collaborative Research Opportunity: The NHLBI Lipoprotein Metabolism Section is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Hydrocarbon-stapled Apolipoprotein Peptide Mimetics for the Treatment of Cardiovascular Diseases and Inflammation. For collaboration opportunities, please contact Denise Crooks, Ph.D. at *crooksd@nhlbi.nih.gov*.

Parvovirus B19 Vaccine

Description of Technology: Parvovirus B19 (B19V) infection causes fifth disease, a disease characterized by rashes to the face and other parts of the body that primarily affects children. However, adults can also develop fifth disease and it can lead to more severe conditions. Patients that are immunocompromised, such as those who are HIV infected, organ transplant recipients, and cancer patients, can be particularly susceptible to more severe outcomes from B19V infection. Infection can also cause anemia and in pregnant women, it can lead to hydrops fetalis.

The subject technologies are expression vectors for the production of B19V VP1 and VP2 capsid proteins. Co-expression of the two proteins produce empty virus-like particles (VLPs) that can be used to develop a vaccine against parvovirus B19 and a packaging system for infectious B19V virus. Different expression vectors have been developed and optimized for expression in insects cells and more recently in mammalian cell lines such as 293, Cos7, Hela cells and 293T cells.

Potential Commercial Applications: Vaccine against parvovirus B19V.

Competitive Advantages: There is currently no B19V vaccine on the market.

Development Stage:

- Early-stage
- Pre-clinical
- Clinical
- In vitro data available
- In vivo data available (animal)
- In vivo data available (human)

Inventors: Neal S. Young, Takashi Shimada, Sachiko Kajigaya, Ning Zhi (NHLBI)

Publications:

1. Bernstein DI, et al. Safety and immunogenicity of a candidate parvovirus B19 vaccine. Vaccine. 2011 Oct 6;29(43):7357–63. [PMID 21807052]
2. Zhi N, et al. Codon optimization of human parvovirus B19 capsid genes greatly increases their expression in nonpermissive cells. J Virol. 2010 Dec;84(24):13059–62. [PMID 20943969]

Intellectual Property:

- HHS Reference No. E–286–1988/2—U.S. Patent No. 5,916,563 issued 29 Jun 1999
- HHS Reference No. E–286–1988/1—U.S. Patent No. 6,001,371 issued 14 Dec 1999; U.S. Patent No. 6,132,732 issued 17 Oct 2000
- HHS Reference No. E–266–2000/0—U.S. Patent No. 6,558,676 issued 06 May 2003
- HHS Reference No. E–011–2010/0—International PCT Appl. No. PCT/US2011/024199 with national stage filings in the U.S. and Europe

Licensing Contact: Kevin W. Chang, Ph.D.; 301–435–5018; *changke@mail.nih.gov*

Collaborative Research Opportunity: The National Heart, Lung, and Blood Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize the technology for producing Parvovirus B19 vaccine. For collaboration opportunities, please contact Cecilia Pazman, Ph.D. at *pazmance@mail.nih.gov*.

Dated May 2, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013–10857 Filed 5–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R13 Conference.

Date: June 19, 2013.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: D. G. Patel, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 756, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7682, *pateldg@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK nGUDMAP U01 Application Review.

Date: July 8, 2013.

Time: 9:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Xiaodu Guo, Md, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 761, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–4719, *guox@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: May 2, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–10856 Filed 5–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Clinical Trials Units for NIAID Networks.

Date: June 5, 2013.

Time: 9:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 235, 6700A Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Betty Poon, PHD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–402–6891, *poonb@mail.nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Clinical Trials Units for NIAID Networks.

Date: June 5, 2013.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 2C21/23, 10401 Fernwood Building, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Uday K. Shankar, PHD, MSC, Scientific Review Officer, Scientific Review Program, DEAS/NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–594–3193, *uday.shankar@nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Clinical Trails Unit for NIAID Networks.

Date: June 6, 2013.

Time: 9:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 2C05, 10401 Fernwood Building, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Robert C. Unfer, PHD, Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700–B Rockledge Dr., MSC–7616, Bethesda, MD 20892–7616, 301–496–2550, *robert.unfer@nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Clinical Trials Units for NIAID Networks.

Date: June 12, 2013.

Time: 9:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 1202, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Betty Poon, PHD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–402–6891, *poonb@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 2, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–10855 Filed 5–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; Conferences on Environmental Health.

Date: June 4, 2013.

Time: 12:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Nat. Inst. of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Leroy Worth, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30/Room 3171, Research Triangle Park, NC 27709, (919) 541–0670, *worth@niehs.nih.gov*.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; Transition to Independence (Careers) Development.

Date: June 6, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Durham Southpoint Hotel, 7007 Fayetteville Road, Durham, NC 27713.

Contact Person: Leroy Worth, Ph.D., Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30/Room 3171, Research Triangle Park, NC 27709, 919/541–0670, *worth@niehs.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: May 2, 2013.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–10870 Filed 5–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Asthma in Older Adults.

Date: May 29, 2013.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jeanette Johnson, Ph.D., Scientific Review Branch, National Institute

on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7705, *JOHNSONJ9@NIA.NIH.GOV.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Mild Cognitive Impairment.

Date: June 5, 2013.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: William Cruce, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7704, *crucew@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: May 1, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–10854 Filed 5–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Use of Oligodeoxynucleotide as Neuroprotectants in Cerebral and Other Ischemic Injury

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. provisional patent application No. 60/176/115 (E–078–2000/0–US–01) filed 1/14/2000; PCT application No. PCT/US01/01122 (E–078–2000/0–PCT–02) filed 1/12/2001; U.S. patent No. 7,521,063 (E–078–2000/1–US–01) filed 07/12/2002 and issued 04/21/2009; U.S. patent No. 7,919,477 (E–078–2000/1–US–02) filed 05/10/2007and issued 04/05/2011; U.S. patent No. 8,232,259 (E–078–2000/1–US–03) filed 02/11/2011 and issued 07/31/2012; E.U. patent No. 1322655 (E–078–2000/0–EP–03) filed 1/12/2001 and issued 11/14/2007 and validated in AT, GB, and IE (E–078–2000/0–AT–05, E–078–2000/0–GB–07, & E–078–2000/0–IE–08) and issued 12/13/2007 as patent No. 6031430 and validated in Germany (E–078–2000/0–DE–06); and E.U. patent application No. 07021557.9 (E–078–2000/0–EP–04) filed 11/05/2007; each entitled ''Oligodeoxynucleotide and Its Use to Induce an Immune Response''; by Klinman et al. (FDA) to Oregon Health Sciences University having a place of business at 3181 SW. Sam Jackson Park Rd. Portland, Oregon 97239. The patent rights in this invention have been assigned to the United States of America.

DATES: Only written comments and/or application for a license that are received by the NIH Office of Technology Transfer on or before June 7, 2013 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Tedd Fenn, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Email: *fennea@mail.nih.gov*; Telephone: 301–435–5031; Facsimile: 301–402–0220.

SUPPLEMENTARY INFORMATION: The prospective worldwide exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The subject patents relate to compositions and methods of use of oligodeoxynucleotides (ODNs) expressing CpG motifs to induce immune responses. These ODNs mimic signals of invading pathogens. ODN motifs trigger immune system responses via Toll-like receptor 9 (TLR9). They also mediate inflammatory responses to tissue injury, such as those responses following ischemic damage to the central nervous system. Structural differences between various ODNs may stimulate distinct cell populations, allowing selective targeting of immune responses for therapeutic purposes. Non-human primate and animal models using specific ODNs for pharmacological preconditioning have shown that ODNs may act therapeutically as neuroprotectants from ischemic damage. These TLR ligands as may be useful therapeutically as neuroprotectants in cerebral ischemic injury.

The field of use may be limited to pharmacological preconditioning against excitotoxic injury, ischemia and/or hypoxia.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 2, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013–10858 Filed 5–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-Up Exclusive Evaluation Option License Agreement: Gene Therapy and Cell-Based Therapy for Cardiac Arrhythmias

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a Start-Up Exclusive Evaluation Option License Agreement to Pace Biologics, LLC, a company having a place of business in Elkridge, Maryland, to practice the inventions embodied in U.S. Provisional Patent Application No. 61/180,491, filed May 22, 2009 (HHS Ref. No. E–134–2009/0–US–01), PCT Patent Application No. PCT/US2010/035823, filed May 21, 2010 (HHS Ref. No. E–134–2009/0–PCT–02), and U.S. Patent Application No. 13/322,066, filed November 22, 2011 (HHS Ref. No. E–134–2009/0–US–03), all entitled ''Engineered Biological Pacemakers.'' The patent rights in these inventions have been assigned to the Government of the United States of America. The territory of the prospective Start-Up Exclusive Evaluation Option License Agreement may be worldwide, and the field of use may be limited to ''Gene therapy and cell-based therapy for cardiac arrhythmias in humans.''

Upon the expiration or termination of the Start-up Exclusive Evaluation Option License Agreement, Pace Biologics will have the exclusive right to execute a Start-Up Exclusive Patent

License Agreement which will supersede and replace the Start-up Exclusive Evaluation Option License Agreement, with no greater field of use and territory than granted in the Start-up Exclusive Evaluation Option License Agreement.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before May 23, 2013 will be considered.

ADDRESSES: Requests for copies of the patent application(s), inquiries, comments and other materials relating to the contemplated Start-Up Exclusive Evaluation Option License Agreement should be directed to: Tara L. Kirby, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4426; Facsimile: (301) 402–0220; Email: *tarak@mail.nih.gov*. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: This invention consists of biological pacemakers engineered to treat arrhythmia by generating a normal heart rhythm. These pacemakers include viral vectors suitable for gene therapy that incorporate Ca^{2+}-activated adenylyl cyclase, as well as cardiac cells or cardiac-like cells derived from embryonic stem cells or mesenchymal stem cells, which are suitable for cell-based therapy.

In contrast to implantable artificial pacemakers, these biological pacemakers are not externally powered, are not subject to interference from other devices, and have a lower risk of infection. They would be particularly appropriate for patients who are not candidates for artificial pacemakers, such as children or those who have had an implantable pacemaker removed due to complications or other problems.

The prospective Start-Up Exclusive Evaluation Option License Agreement is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective Start-Up Exclusive Evaluation Option License Agreement and a subsequent Start-Up Exclusive Patent License Agreement may be granted unless the NIH receives written evidence and argument, within fifteen (15) days from the date of this published notice that establishes, that the grant of the contemplated Start-Up Exclusive Evaluation Option License Agreement would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Start-Up Exclusive Evaluation Option License Agreement. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 2, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013–10859 Filed 5–7–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Announcement of Requirements and Registration for the National Radiological and Nuclear Detection Challenge

AGENCY: Domestic Nuclear Detection Office, DHS.

ACTION: Notice.

SUMMARY: DNDO announces the National Radiological and Nuclear Detection (Rad/Nuc) Challenge, a participation challenge being conducted under the America Competes Reauthorization Act, for state, local, and tribal law enforcement, other first responders, public safety officials, and Civil Support Team members.

DATES: The Rad/Nuc Challenge will be held from August 20 through August 22, 2013.

ADDRESSES: The Rad/Nuc Challenge will be hosted at the I.G. Brown Air National Guard Training and Education Center, Alcoa, Tennessee, near Knoxville.

FOR FURTHER INFORMATION CONTACT: Timothy Smith, (202) 254–7297, *Radnucchallenge@hq.dhs.gov*. To register for and find additional information about the Rad/Nuc challenge, visit *http://www.radnucchallenge.org*.

SUPPLEMENTARY INFORMATION:

General

The Department of Homeland Security (DHS), Domestic Nuclear Detection Office (DNDO), announces the National Radiological and Nuclear Detection (Rad/Nuc) Challenge, a participation challenge authorized under 15 U.S.C. 3719(c)(3), for state, local, and tribal law enforcement, other first responders, public safety officials, and Civil Support Team members. The purpose of the Rad/Nuc Challenge is to increase proficiency, improve Concepts of Operations, and promote proper use of Radiation and Nuclear Detection (RND) equipment by state and local agencies in support of the domestic RND mission to prevent the illicit use and/or movement of radioactive materials within the United States.

The Rad/Nuc Challenge will consist of a competitive RND search exercise held over a three-day period. The competition is designed to develop and recognize enhanced RND search skills, train on the use of various pieces of RND equipment, and influence vendors and developers to adapt and improve RND equipment capability and suitability for field use.

The event will be hosted at the I.G. Brown Air National Guard Training and Education Center located in Alcoa, Tennessee, near Knoxville. Equipment specific and RND search refresher training will be provided for all competitors on the first day of the event prior to the start of the competition.

I. Subject of Challenge Competition

The purpose of the Rad/Nuc Challenge is to further DNDO's vision of a Nation ready to detect and interdict terrorist radiological and/or nuclear threats by the effective and efficient integration of capabilities and resources of the Global Nuclear Detection Architecture (GNDA). Specifically, the Rad/Nuc Challenge will serve to coordinate implementation of the domestic portion of the GNDA, strengthen its operational relationships, and improve detection capabilities across the GNDA. The Rad/Nuc Challenge will provide a mechanism to improve radiation detection capabilities of Federal, state, local, and tribal stakeholders through competitive exercise, increased awareness and cooperation, and first-hand interaction with RND equipment vendors and developers. The Rad/Nuc Challenge will exploit the proven success and cost-effectiveness of trade shows and challenge competitions to advance capabilities in the RND field.

The Rad/Nuc Challenge is an RND proficiency competition. Even though it is designed to incorporate specific RND job skills or tasks, it may be necessary to deviate from, or be innovative in the application of, certain existing protocols and procedures in order to obtain the

best overall result and win the competition.

Two components, the Maze and the Container Search, make up the Rad/Nuc Challenge competitive exercise. This RND exercise will be organized in flights and heats of competitors. Flights will be composed of multiple heats. Each heat may include four or more competitors, with each competitor occupying one lane on the RND search course. Sources may be changed and/or repositioned between flights and/or heats to allow competitors to view the competition of other flights and heats. All competitors within a given flight will be sequestered and called to the course when their heat is ready to start. Advancing through each round of the competition will be based on a competitor's detection and identification accuracy and RND search course completion time. Time penalties may be incurred for radiation source detection and identification errors. Competitor times will be measured at least to the 0.1 of a second by an automated timing system.

Radiological sources employed for the Rad/Nuc Challenge will include isotopes common to typical detection instrument libraries, but may include isotopes that are not in some libraries. A list of actual sources that may be encountered during the event will be communicated to registered competitors prior to the competition. Source strengths will be sufficient such that most competitors should be able to detect and identify the sources using a typical personal radiation detector (PRD) and/or a radioisotope identification device (RIID).

All competitors will have the opportunity to participate in a practice round and the first elimination round. Competitor RND search completion times in each elimination round, including any time penalties incurred, will be used to determine which competitors advance. A maximum time limit will be set. Competitors who do not finish within the time limit will receive the maximum time plus applicable penalties.

Competitors will be required to use commercially available RND equipment to detect, localize, and identify radiation sources. Competitors may also be required to determine and indicate relative radiation source strengths. Competitors are encouraged to use their own RND equipment. However, a limited amount of RND equipment will be available for use by competitors at the event.

Time penalties will be assessed for radiation detection, localization, identification, and relative source strength inaccuracies. Competitors will be required to balance accuracy and speed to obtain the best possible time and win the competition.

Below we describe the Maze and Container Search components of the exercise in greater detail.

A. The Maze

The Maze requires locating radiation sources hidden among a number of identical tables. The tables in each lane will be arranged in identical patterns. A pre-determined number of radiological sources will be placed in boxes in each of the lanes. Each competitor or team will compete in their own lane. (See Figure 1 for a possible layout arrangement.)

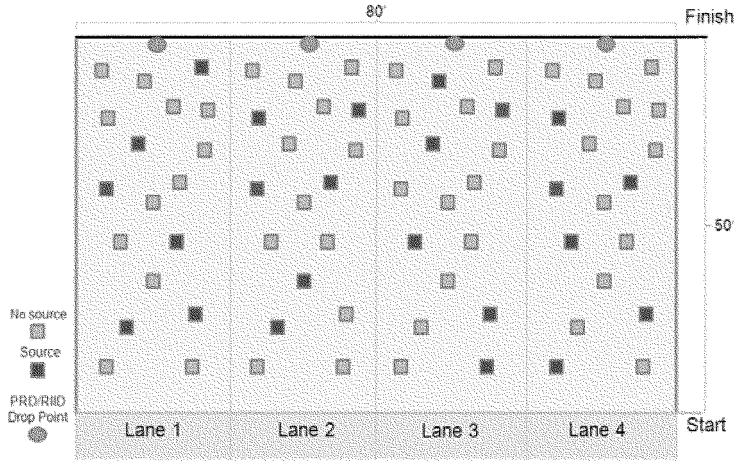

Figure 1 -- Maze Layout

The sources will vary in size and by isotope within a single lane, but only one primary isotope will be in any box. Each lane will have an identical mix of sources. Each competitor will have a marking mechanism to clearly identify the boxes containing sources. These markers will be clearly visible to the referees and spectators. Background measurements will be taken before the event to identify any Naturally Occurring Radioactive Materials (NORM) or spectators/participants with medical isotopes in the area which might affect the competition.

B. The Container Search

The Container Search requires each competitor to detect and locate sources hidden inside shipping containers. Single or multiple sources may be placed at various heights above the ground, but along the centerline of the containers. Each competitor will compete in their own lane on either side of the container row. (See Figure 2 for a possible layout arrangement.)

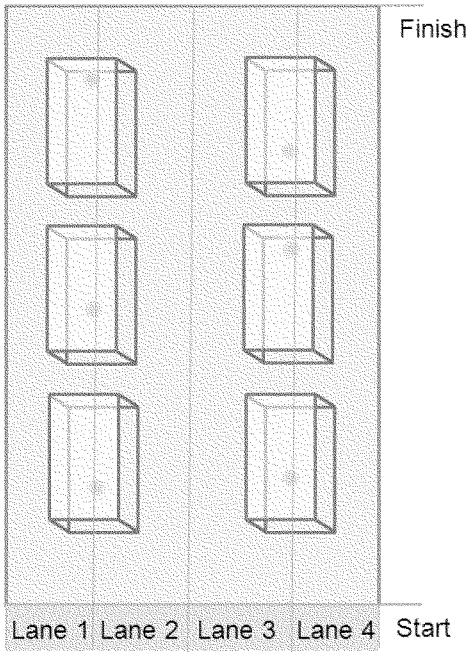

Figure 2 -- Container Layout Search

The containers will be placed in rows end-to-end, spaced so that access is possible between containers to allow entry for source placement and position changes. The side of each container will have a grid for competitors to use to indicate the source's location. Sources positioned at the centerline of containers will be of sufficient strength to be detected by most competitors using a typical PRD or RIID. Background measurements will be taken before the event to identify any NORM or spectators/participants with medical isotopes in the area which might affect the competition.

II. Eligibility To Participate in the Competition

Pursuant to 15 U.S.C. 3719, American COMPETES Reauthorization Act of 2010, Public Law 111–358, the Rad/Nuc Challenge is open only to (i) Individuals who are at least 18 years of age and citizens or permanent residents of the United States as of the time of entry, and (ii) teams of eligible individuals, where each team member meets the eligibility requirements for individual contestants.

The Rad/Nuc Challenge is also limited to Civil Support Team members, state, local and tribal law enforcement, other first responders, and public safety officials. Other individuals, including Federal employees or contractors whose work deals directly with radiological and nuclear detection or detection equipment, may be eligible to be non-competitive participants in the Rad/Nuc Challenge. This means that unless otherwise ineligible, such individuals may participate, but will not be eligible for an award, and will not compete directly against the registered state, local and tribal law enforcement, other first responders, public safety officials, and Civil Support Team competitors for non-monetary awards in the competitive exercise.

The following individuals and/or teams are not eligible, regardless of whether or not they meet the criteria set forth above: (i) The sponsoring agency, contractor, or other organization involved with the design, production, promotion, execution, or distribution of the competition (collectively ''Promotion Entities''); all employees, representatives, and agents of such entities, and immediate family or household members of any such employee, representative, or agent; (ii) any individual and/or team involved with the design, production, promotion, execution, or distribution of the competition and each member of any such individual's immediate family or household; (iii) any individual and/or team that employs any judge or that otherwise has a material business relationship or affiliation with any judge; (iv) any Federal entity or Federal employee acting within the scope of their employment, or as may otherwise be prohibited by Federal law; and (v) any individual and/or team that used Federal facilities or consulted with Federal employees to develop their solution, unless the facilities and employees were made available to all participants on an equitable basis.

III. Registration for Competitors and Attendees

All Rad/Nuc Challenge competitors and attendees will be required to register at *www.radnucchallenge.org.* The Web site will be open for registration on May 8, 2013. Competitors and attendees are encouraged to visit the Web site periodically for updates on the event and to register for other Rad/Nuc Challenge events such as training, technical briefings, and special exhibitions which may have limited space available. These events will be made available on a first-come, first-served basis.

In order to encourage broad participation and early registration, DNDO will offer a travel reimbursement for the first 250 registered state, local and tribal law enforcement, other first responders, public safety officials, and Civil Support Team competitors. To encourage broad agency participation, there will be a limit to the number of competitors from a single agency that will be eligible for travel reimbursement. Once travel obligations are made for the first 250 registered state, local and tribal law enforcement, other first responders, public safety officials, and Civil Support Team competitors, the travel reimbursement will no longer be available and a notice will be posted on the Rad/Nuc Challenge Web site.

All Rad/Nuc Challenge non-competitor attendees, including exhibitors, briefers, and observers, will be required to register and may be required to pay a nominal fee. Exhibitors may also be required to pay an additional fee to cover facility and other expenses related to the exhibition. The total number of attendees may be limited by the venue or exhibit area constraints so early registration is strongly encouraged.

IV. Basis on Which Winners Will Be Selected

Advancement beyond the first round of each event is based on the competitor's RND proficiency based on their overall score. A competitor's score will be determined by the RND search course completion time as measured by an automated timing system. Penalties may be assessed by adding time to the competitor's raw completion time for not locating all sources, incorrectly identifying sources, reporting sources not present, inaccurately localizing sources, and failing to navigate the RND search course properly. Competitors with the best overall score based on speed and accuracy will be declared the winners of each heat and, ultimately, through elimination rounds, winner of the Rad/Nuc Challenge.

V. Prize

Winner(s) of the Rad/Nuc Challenge will be recognized for RND performance excellence and expertise through non-monetary awards. The winners of each component of the competitive exercise and the overall winner will receive a trophy and certificate of achievement. The winners' name, agency, equipment used, and winning score for each event will also be posted on the Rad/Nuc Challenge Web site.

VI. Additional Information

The Rad/Nuc Challenge will also provide access to exhibits featuring state of the art technologies supporting the RND mission, advanced technology demonstrations that showcase capability enhancing technologies under development, and an information exchange forum consisting of RND mission related briefings, panel discussions, and workshops. These forums will solicit user input on RND equipment operational requirements, and share RND mission best practices and lessons learned.

Exhibition space will be available to all Rad/Nuc Challenge participants, including vendors, academia, national laboratories, and government agencies to showcase advanced capabilities, RND and other mission related equipment, and innovations in the RND mission area. Availability is on a first come, first serve basis. User fees may apply.

For registration and other information, see the event Web site at *www.radnucchallenge.org* or contact Timothy Smith, DHS, DNDO, by email at *radnucchallenge@hq.dhs.gov*.

Authority: 15 U.S.C. 3719.

Rafael Borras,

Under Secretary for Management.

[FR Doc. 2013–10928 Filed 5–7–13; 8:45 am]

BILLING CODE 9110–9D–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2013–0222]

Information Collection Request to Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an approval for the following collection of information: 1625–NEW, U.S. Coast Guard Non-Appropriated Fund Employment Application. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before July 8, 2013.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2013–0222] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT). To avoid duplicate submissions, please use only one of the following means:

(1) *Online: http://www.regulations.gov.*

(2) *Mail:* DMF (M–30), DOT, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(3) *Hand delivery:* Same as mail 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:* 202–493–2251. To ensure your comments are received in a timely manner, mark the fax, to 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 this 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.*

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–611), ATTN Paperwork Reduction Act Manager, US Coast Guard, 2100 2ND ST SW STOP 7101, Washington DC 20593–7101.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–475–3929, for questions on these documents. Contact Ms. Barbara Hairson, 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 this ICR 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. In response to your comments, we may revise this ICR

or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2013–0222], and must be received by July 8, 2013. 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–2013–0222], 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 your 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–2013–0222'' in the ''Keyword'' box. If you submit your comments by mail or delivery, submit them in an unbound format, no larger than 8–½ by 11 inches, suitable for copying and electronic filing. If you submit them 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 ''Keyword'' box insert ''USCG–2013–0222'' 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.

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).

Information Collection Request

Title: U.S. Coast Guard Non-Appropriated Fund Employment Application.

OMB Control Number: 1625–NEW.

SUMMARY: The USCG Non-Appropriated Employment Application form will be used to collect applicant qualification information associated with vacancy announcements both online and manually. The manual form will allow individuals without resumes, computers and/or those with limited digital literacy equal access to apply for employment opportunities with the Coast Guard Non-appropriated fund (NAF) workforce and will fill the gap created by the cancellation of the Optional Application for Federal Employment, Form OF–612, OMB No. 3206–0219.

Need: The Optional Application for Federal Employment, Form OF–612, was cancelled and the information is now collected in USA Jobs. The NAF personnel system does not utilize USA Jobs because of the high cost and high turnover rate and thus relied heavily on form OF–612 for applicants.

Non-Appropriated Fund (NAF) employment is Federal employment but does not confer civil service status. The funds used to pay the salaries of NAF employees are self-generated by the Coast Guard Exchange and other Coast Guard Non-Appropriated Fund Instrumentalities (NAFI). Seventy five percent of the 1400 plus NAF positions are low-paid, entry level positions. According to the U.S. Federal Communications Commission, 66 million Americans lack the basic digital skills needed to use a computer and the Internet. This form will allow electronic and paper submission for employment for applicants without resumes.

Forms: CG–1227B.

Respondents: Public applying for positions with the USCG Non-appropriated fund workforce.

Frequency: Per vacancy announcement.

Burden Estimate: The estimated annual burden is 5540 hours.

Dated: April 29, 2013.

R. E. Day,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Command, Control, Communications, Computers and Information Technology.

[FR Doc. 2013–10881 Filed 5–7–13; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2013–0125]

Waterway Suitability Assessment for Expansion of Liquefied Gas Terminals; Beaumont, TX

AGENCY: Coast Guard, DHS.

ACTION: Notice and request for comments.

SUMMARY: In accordance with Coast Guard regulations, Martin Operating Partnership LP has submitted a Letter of Intent and a Waterway Suitability Assessment to the Coast Guard Captain of the Port, Port Arthur regarding the company's proposed expansion of its Liquefied Hazardous Gas (LHG) facility in Beaumont, Texas, and increased LHG marine traffic in the associated waterway. The Coast Guard is notifying the public of this action to solicit public comments on the proposed increase in LHG marine traffic in Beaumont, Texas.

DATES: Comments and related material must be received on or before June 7, 2013.

ADDRESSES: You may submit comments identified by docket number USCG–2013–0125 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail or Delivery:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these three methods. See the

''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Mr. Scott Whalen, U.S. Coast Guard; telephone 409–719–5083, email *scott.k.whalen@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to submit comments and related material in response to this notice. All comments received will be posted without change, to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting comments: If you submit a comment, please include the docket number for this notice (USCG–2013–0125), and provide a reason for each suggestion or recommendation. You may submit your comments and material online at *http://www.regulations.gov,* or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comments. 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 Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* type the docket number (USCG–2013–0125) in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Submit a Comment'' on the line associated with this notice.

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 them 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.

Viewing comments and documents: To view comments, go to *http://www.regulations.gov,* type the docket number (USCG–2013–0125) 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.

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 meeting: We do not now plan to hold a public meeting, but you may submit a request for one, using one of the methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Basis and Purpose: Under 33 CFR 127.007(a), an owner or operator planning new construction to expand or modify marine terminal operations in an existing facility handling Liquefied Natural Gas (LNG) OR Liquefied Hazardous Gas (LHG), where the construction, expansion, or modification would result in an increase in the size and/or frequency of LNG or LHG marine traffic on the waterway associated with the facility, must submit a Letter of Intent (LOI) to the COTP of the zone in which the facility is located. Under 33 CFR 127.007(e), an owner or operator planning such an expansion must also file or update a Waterway Suitability Assessment (WSA) that addresses the proposed increase in LNG or LHG marine traffic in the associated waterway. Martin Operating Partnership's Stanolind Cut Terminal in Beaumont, Texas submitted an LOI on January 25, 2013, and a WSA on January 25, 2013, regarding the company's proposed expansion of its LHG facility in Beaumont, Texas.

Under 33 CFR 127.009, after receiving an LOI, the COTP issues a Letter of Recommendation (LOR) as to the suitability of the waterway for LNG or LHG marine traffic to the appropriate jurisdictional authorities. The LOR is based on a series of factors outlined in 33 CFR 127.009 that related to the physical nature of the affected waterway and issues of safety and security associated with LNG or LHG marine traffic on the affected waterway.

The purpose of this notice is to solicit public comments on the proposed increase in LHG marine traffic in Beaumont, Texas. The Coast Guard believes that input from the public may be useful to the COTP with respect to development of the LOR. Additionally, the Coast Guard tasked the Area Maritime Security Committee, Port Arthur, Texas and the Southeast Texas Waterways Advisor Committee (SETWAC) with forming a subcommittee comprised of affected port users and stakeholders. The goal of these subcommittees will be to gather information to help the COTP assess the suitability of the associated waterway for increased LHG marine traffic as it relates to navigational safety and security.

On January 24, 2011, the Coast Guard published Navigation and Vessel Inspection Circular (NVIC) 01–2011, ''Guidance Related to Waterfront Liquefied Natural Gas (LNG) Facilities.'' NVIC 01–2011 provides guidance for owners and operators seeking approval to build and operate LNG facilities. While NVIC 01–2011 is specific to LNG, it provides useful process information and guidance for owners and operators seeking approval to build and operate LHG facilities as well. The Coast Guard will refer to NVIC 01–2011 for process information and guidance in evaluating Martin Operating Partnership LP's WSA. A copy of NVIC 01–2011 is available for viewing in the public docket for this notice and also on the Coast Guard's Web site at *http://www.uscg.mil/hq/cg5/nvic/2010s.asp.*

This notice is issued under authority of 33 U.S.C. 1223–1225, Department of Homeland Security Delegation Number 0170.1(70), 33 CFR 127.009, and 33 CFR 103.205.

Dated: April 1, 2013.

J. M. Twomey,

Commander, U.S. Coast Guard, Acting Captain of the Port, Port Arthur.

[FR Doc. 2013–10880 Filed 5–7–13; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5683–N–35]

Notice of Submission of Proposed Information Collection to OMB; Section 901 Notice of Intent and Fungibility Plan for Combining Public Housing Capital or Operating Funds, or Housing Choice Voucher Funds To Assist Displaced Families and Address Damages

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. HUD is soliciting public comments on the subject proposal.

DATES: *Comments Due Date: June 7, 2013.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2577–0245) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov* fax: 202–395–5806.

FOR FURTHER INFORMATION CONTACT: Colette Pollard., Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov.* or telephone (202) 402–3400. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that the HUD has submitted to OMB a request for approval of the Information collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (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; (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 collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This notice also lists the following information:

Title of Proposed: Section 901 Notice of Intent and Fungibility Plan for Combining Public Housing Capital or Operating Funds, or Housing Choice Voucher Funds to Assist Displaced Families and Address Damages.

OMB Approval Number: 2577–0245.

Form Numbers: None.

Description of the need for the information and proposed use:

The Notice of Intent is necessary for HUD to be informed about which eligible PHAs elect to invoke the funding flexibility authorized by section 901 of the Emergency Supplemental Appropriations (Pub. L. 109–148). The Fungibility Plan and Reports are necessary for HUD to know how eligible PHAs plan to reallocate and spend these funds, the rate such funds are obligated and expended, and the results in using this funding flexibility. Fungibility Plans proposing to use Section 901 flexibility and funding to develop new housing units under Capital Fund mixed-finance uses or for development of HCV project-based units were required to include new development proposals following the format required by 24 CFR 941.606 or mixed-finance rules as appropriate. Fungibility Plans proposing to use Section 901 flexibility to pay for public housing renovations were required to submit CFP Annual Statements identifying work items and costs. These collections are approved under separate OMB numbers. Under Section 901, funds from one of the programs identified above could be used for another program's purposes, but were required to follow the rules of the program in which the funds would be used. HUD has not received any new Section 901 Fungibility Plans since 2009, which was the last year Congress extended this funding flexibility to address the impacts of Hurricanes Rita and Katrina. Some PHAs have used the fungibility plan format to submit revisions to their originally approved plans.

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response:

Notification of Intent and Fungibility Plan. This is a one-time submission estimated to take 40 hours for each of up to twelve eligible PHAs that submitted plans from 2006 through 2009. PHAs may also use this format to request HUD approval for subsequent plan revisions. The original burden estimate for this information collection was 6,624 hours assuming all ninety-six PHAs in the areas impacted by Hurricanes Katrina and Rita would opt to use it. A later burden estimate of 1,248 hours was submitted, when in 2006, only eight out of ninety-six eligible PHAs submitted plans to use Section 901 flexibility. In 2007, seven out of the eight 2006 PHAs and one new PHA submitted plans to use Section 901 flexibility. In 2008, seven out of the nine 2006 and 2007 PHAs and three new PHAs submitted plans to use Section 901 flexibility. Ten or fewer respondents have submitted plans to use Section 901 flexibility each year. One PHA submitted a plan in 2009, the last year in which Section 901 funding flexibility was available. As a result, the estimate of burden hours for new fungibility plans has been removed. A total of ten different PHAs have been approved to use and must report the results of Section 901 flexibility. A new estimate of burden for Section 901 Notifications of Intent and Fungibility Plans or revisions, and subsequent periodic reporting is 1,680 hours based on requirements for 10 PHAs to prepare and submit these documents.

Status: Extension without change of a currently approved collection.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: May 2, 2013.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2013–10942 Filed 5–7–13; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[DR.5B711.IA000813]

Indian Gaming

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Approved Tribal-State Class III Gaming Compact.

SUMMARY: This notice publishes the approval of an amendment to the Class III Tribal-State Gaming Compact between the Menominee Indian Tribe of Wisconsin and the State of Wisconsin (Amendment).

DATES: *Effective Date:* May 8, 2013.

FOR FURTHER INFORMATION CONTACT: Paula L. Hart, Director, Office of Indian

Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under Section 11 of the Indian Gaming Regulatory Act (IGRA) Public Law 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. On March 19, 2013, the Menominee Indian Tribe of Wisconsin (Tribe) and the State of Wisconsin submitted an Amendment for review and approval. The amendment adds the language ''or the government of an Indian tribe as defined in 25 U.S.C. 2703(5),'' for purposes of including tribal governments in the compact's list of entities that are exempt from obtaining a State-issued certificate to finance the Tribe's gaming-related facilities.

Dated: May 1, 2013.

Kevin K. Washburn,

Assistant Secretary—Indian Affairs.

[FR Doc. 2013–10923 Filed 5–7–13; 8:45 am]

BILLING CODE 4310–4N–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[DR.5B711.IA000813]

Land Acquisitions; Cowlitz Indian Tribe

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Final Agency Determination.

SUMMARY: The Assistant Secretary—Indian Affairs made a final agency determination to acquire approximately 151.87 acres of land into trust for gaming and other purposes for the Cowlitz Indian Tribe on April 22, 2013.

FOR FURTHER INFORMATION CONTACT: Paula L. Hart, Director, Office of Indian Gaming, Bureau of Indian Affairs, MS–3657 MIB, 1849 C Street NW., Washington, DC 20240; Telephone (202) 219–4066.

SUPPLEMENTARY INFORMATION: This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 Departmental Manual 8.1, and is published to comply with the requirements of 25 CFR 151.12(b) that notice be given to the public of the Secretary's decision to acquire land in trust at least thirty (30) days prior to signatory acceptance of the land into trust.

On December 17, 2010, the Assistant Secretary—Indian Affairs issued a Record of Decision (2010 ROD) announcing a final determination to acquire in trust approximately 151.87 acres of land and to proclaim the land to be the Cowlitz Indian Tribe's reservation. Notice of that decision was published in the **Federal Register** on January 4, 2011, 76 FR 377 (2011). That decision was challenged in the United States District Court for the District of Columbia. On March 13, 2013, the district court remanded the matter to the Department with instructions to rescind the 2010 ROD, and ordered the Department to issue a new ROD within sixty (60) days of the date of the decision unless good cause was shown why the Department could not do so.

On April 22, 2013, the Assistant Secretary—Indian Affairs rescinded the 2010 ROD and issued a new ROD announcing the decision to acquire in trust approximately 151.87 acres of land in trust for the Cowlitz Indian Tribe and issue a reservation proclamation under the authority of the Indian Reorganization Act of 1934, 25 U.S.C. 465 and 467. We have determined that the Cowlitz Indian Tribe's request meets the requirements of the Indian Gaming Regulatory Act's ''initial reservation'' exception, 25 U.S.C. 2719(b)(1)(B)(ii), to the general prohibition contained in 25 U.S.C. 2719(a) on gaming on lands acquired in trust after October 17, 1988. The land is located in Clark County, Washington, and will be used for gaming and other purposes.

The 151.87 acre parcel located in Clark County, Washington, is described as follows:

PARCEL I

BEGINNING at the intersection of the West line of Primary State Highway No. 1 and the East line of the Southeast quarter of Section 5, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington; thence Northerly along said West line of Primary State Highway No. 1 a distance of 1307.5 feet to the Point of Beginning of this description; thence West 108.5 feet to an angle point thereon; thence Northerly along the fence 880.5 feet to the center line of a creek; thence Northerly along said creek 443 feet to the West line of Primary State Highway No. 1; thence Southerly along said West line of Highway to the Point of Beginning.

EXCEPT that portion conveyed to the State of Washington by Auditor's File Nos. G 450664 and G 147358.

PARCEL II

That portion of the following described land lying West of the Westerly line of Interstate 5, formerly known as Pacific Highway, in Section 9, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington.

The North half of the Southwest quarter of the Northwest quarter any the South half of the Northwest quarter of the Northwest quarter of Section 9, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington.

EXCEPT any portion lying within NW 31st Avenue.

ALSO EXCEPT that portion thereof acquired by the State of Washington by deed recorded under Auditor's File Nos. G 140380 and D 95767.

PARCEL III

BEGINNING at the Northwest corner of the Northeast quarter of the Northeast quarter of Section 8, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington; and running thence East 390 feet to the Point of Beginning; thence East 206 feet; thence South 206 feet; thence West 206 feet; and thence North to the Point of Beginning.

EXCEPT that portion lying within the right of way of NW 319th Street.

PARCEL IV

All that part of the Southeast quarter of Section 5, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington, lying West of Primary State Road No. 1 (Pacific Highway).

EXCEPT the Henry Ungemach tract recorded in Volume 76 of Deeds, page 33, records of Clark County, Washington, described as follows:

BEGINNING at a point 19.91chains North of the Southwest corner of said Southeast quarter; thence East 13.48 chains to creek; thence Northerly along creek to North line of said Southeast quarter at a point 6.66 chains West of the Northeast corner thereof; thence West to Northwest corner of said Southeast quarter; thence South 19.91 chains to the Point of Beginning.

ALSO EXCEPT the John F. Anderson tract as conveyed by deed recorded under Auditor's File No. F 38759, records of Clark County, Washington, described as follows:

BEGINNING at the Northwest corner of the Southwest quarter of the Southeast quarter of Section 5, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington; and running thence East

514 feet; thence Southerly 340 feet; thence Northwesterly 487 feet to a point 196 feet due South of the Point of Beginning; thence North to the Point of Beginning.

ALSO EXCEPT that tract described as follows:

BEGINNING at a point 26 rods and 9 feet West of the Southeast corner of Section 5, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington; and running thence West 20 rods to County Road; thence North 182 feet; thence East 20 rods; thence South 182 feet to the Point of Beginning.

ALSO EXCEPT a certain reserved tract described as follows:

BEGINNING at the intersection of the West line of Primary State Highway No. 1 (Pacific Highway) and the East line of the Southeast quarter of said Section 5, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington; thence Northerly along said West line of Primary State Highway No. 1, a distance of 1307.5 feet to the True Point of Beginning of this description; thence West 108.5 feet to an angle point therein; thence Northerly along fence 880.5 feet to center line of creek, thence Northeasterly along said creek 443 feet, more or less, to the West line of Primary State Highway No. 1; thence Southerly along said West line of highway to the True Point of Beginning.

ALSO EXCEPT that portion thereof lying with Primary State Highway No. 1 (SR–5) as conveyed to the State of Washington by deed recorded under Auditor's File Nos. G 458085, G 143553 and D 94522.

ALSO EXCEPT any portion lying within NW 319th Street and Primary State Highway No. 1.

PARCEL V

A portion of the Northwest quarter of the Northeast quarter of Section 8, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington, described as follows:

BEGINNING at the Northwest corner of the Northeast quarter of Section 8; thence South along the West line of the Northeast quarter of said Section 8, 1320 feet, more or less, to the Southwest corner of the Northwest quarter of said Northeast quarter; thence East along the South line to a point 830 feet West of the Southeast corner of the Northwest quarter of said Northeast quarter; thence North parallel with the East line of said Northeast quarter to a point 600 feet South of the North line of said Northeast quarter; thence East parallel with the North line of said Northeast quarter 370 feet; thence North parallel with the East line of said Northeast quarter 600 feet to the North line of said Section 8; thence West along the North line of said Section 8 to the Point of Beginning.

EXCEPT that portion lying within NW 319th Street.

ALSO EXCEPT the following described tract:

A portion of the Northwest quarter of the Northeast quarter of Section 8, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington, described as follows:

BEGINNING at the Northwest corner of the Northeast quarter of said Section 8; thence South along the West line of the Northeast quarter of said Section 8, 1320 feet, more or less, to the Southwest corner of the Northwest quarter of said Northeast quarter; thence East along the South line to a point 830 feet West of the Southeast corner of the Northwest quarter of said Northeast quarter; thence North, parallel with the East line of said Northeast quarter to a point 600 feet South of the North line of said Northeast quarter; thence East, parallel with the North line of said Northeast quarter, 370 feet, said point being the True Point of Beginning of the tract herein described; thence West parallel with the North line of said Northeast quarter, a distance of 457 feet; thence North parallel with the West line of said Northeast quarter, a distance of 240 feet; thence East parallel with the North line of said Northeast quarter, a distance of 157.0 feet; thence North, parallel with the West line of said Northeast quarter, a distance of 360 feet, more or less, to the North line of said Northeast quarter; thence East, along said North line, a distance of 300 feet; thence South, parallel with the West line of said Northeast quarter, a distance of 600 feet, more or less, to the True point of Beginning.

PARCEL VI

A portion of the Northwest quarter of the Northeast quarter of Section 8, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington, described as follows:

BEGINNING at the Northwest corner of the Northeast quarter of said Section 8, thence South along the West line of the Northeast quarter of said Section 8; 1320 feet, more or less, to the Southwest corner of the Northwest quarter of said Northeast quarter; thence East along the South line to a point 830 feet West of the Southeast corner of the Northwest quarter of said Northeast quarter; thence North, parallel with the East line of said Northeast quarter to a point 600 feet South of the North line of said Northeast quarter; thence East, parallel with the North line of said Northeast quarter 370 feet to a point, said point being True Point of Beginning of the tract herein described; thence West, parallel with the North line of said Northeast quarter, a distance of 457 feet; thence North, parallel with the West line of said Northeast quarter, a distance of 240 feet; thence East, parallel with the North line of said Northeast quarter, a distance of 157.0 feet; thence North, parallel with the West line of said Northeast quarter, a distance of 360 feet, more or less, to the North line of said Northeast quarter; thence East, along said North line, a distance of 300 feet; thence South, parallel with the West line of said Northeast quarter, a distance of 600 feet, more or less, to the True Point of Beginning.

PARCEL VII

The East 830 feet of the Northwest quarter of the Northeast quarter of Section 8, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington.

EXCEPT the West 370 feet to the North 600 feet thereof.

ALSO EXCEPT that portion of the remainder thereof, lying within NW 319th Street.

PARCEL VIII

The Northeast quarter of the Northeast quarter of Section 8, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington.

EXCEPT that portion of said premises, described as follows:

BEGINNING at a point 612 feet East of the Northwest corner of said Northeast quarter of the Northeast quarter of said Section 8; thence South 191.0 feet; thence East 228.0 feet; thence North 191.0 feet; thence West 228.0 feet to the Point of Beginning.

EXCEPT that portion of said premises, described as follows:

BEGINNING at a point 390.0 feet East of the Northwest corner of said Northeast quarter of the Northeast quarter of said Section 8; thence East 206.0 feet; thence South 206.0 feet: thence West 206.0 feet; thence North 206.0 feet to the Point of Beginning.

EXCEPT that portion of said premises lying within Pekin Ferry County Road, and

EXCEPT that portion of said premises lying within County Road No. 25;

EXCEPT that portion conveyed to the State of Washington by deed recorded under Auditor's File Nos. G 143551 and G 499101.

EXCEPT that portion conveyed to the State of Washington for Interstate 5.

EXCEPT that portion conveyed to James Fisher and wife, by instrument recorded under Auditor's File No. G 699690, described as follows:

BEGINNING at the Southeast corner of the Northeast quarter of the Northeast

quarter of Section 8, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington; thence North 200 feet; thence West 435 feet; thence South 200 feet to a point on the South line of the Northeast quarter of the Northeast quarter of said Section; thence East 435 feet to the Point of Beginning.

PARCEL IX

That portion of the Northeast quarter of the Northeast quarter of Section 8, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington; described as follows:

BEGINNING at a point 612 feet East of the Northwest corner of the Northeast quarter of the Northeast quarter of Section 8, Township 4 North, Range 1 East of the Willamette Meridian, Clark County, Washington; thence South 191 feet; thence East 228 feet; thence North 191 feet; thence West 228 feet to the Point of Beginning.

EXCEPT County Roads.

ALSO EXCEPT that portion thereof conveyed to the State of Washington by deed recorded under Auditor's File Nos. G 500929 and G 143551.

Dated: April 26, 2013.

Kevin K. Washburn,

Assistant Secretary—Indian Affairs.

[FR Doc. 2013–10924 Filed 5–7–13; 8:45 am]

BILLING CODE 4310–4N–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNM940000. L1420000.BJ0000]

Notice of Filing of Plats of Survey, New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey.

SUMMARY: The plats of survey described below are scheduled to be officially filed in the New Mexico State Office, Bureau of Land Management, Santa Fe, New Mexico, thirty (30) calendar days from the date of this publication.

FOR FURTHER INFORMATION CONTACT: These plats will be available for inspection in the New Mexico State Office, Bureau of Land Management, 301 Dinosaur Trail, Santa Fe, New Mexico. Copies may be obtained from this office upon payment. Contact Marcella Montoya at 505–954–2097, or by email at *mmontoya@blm.gov*, for assistance. 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.

SUPPLEMENTARY INFORMATION:

Indian Meridian, Oklahoma (OK)

The plat, representing the dependent resurvey and survey in Township 1 South, Range 3 East, of the Indian Meridian, accepted March 11, 2013, for Group 216 OK.

New Mexico Principal Meridian, New Mexico (NM)

The plat, representing the dependent resurvey and survey in Township 14 South, Range 11 West, of the New Mexico Principal Meridian, NM, accepted March 11, 2013, for Group 1135 NM.

The plat, representing the dependent resurvey and survey of the Antonio Martinez Grant, in the New Mexico Principal Meridian, NM, accepted March 18, 2013, for Group 1126 NM.

The plat, representing the dependent resurvey and survey in Township 14 & 15 North, Range 4 West, of the New Mexico Principal Meridian, NM, accepted April 1, 2013, for Group 1140 NM.

The plat, representing the dependent resurvey and survey in Township 17 North, Range 5 East, of the New Mexico Principal Meridian, NM, accepted April 15, 2013, for Group 1142 NM.

These plats are scheduled for official filing 30 days from the notice of publication in the **Federal Register**, as provided for in the BLM Manual Section 2097—Opening Orders. Notice from this office will be provided as to the date of said publication. If a protest against a survey, in accordance with 43 CFR 4.450–2, of the above plats is received prior to the date of official filing, the filing will be stayed pending consideration of the protest.

A plat will not be officially filed until the day after all protests have been dismissed and become final or appeals from the dismissal affirmed.

A person or party who wishes to protest against any of these surveys must file a written protest with the Bureau of Land Management New Mexico State Director stating that they wish to protest.

A statement of reasons for a protest may be filed with the Notice of Protest to the State Director or the statement of reasons must be filed with the State Director within thirty (30) days after the protest is filed.

Robert A. Casias,

Deputy State Director, Cadastral Survey/ GeoSciences.

[FR Doc. 2013–10906 Filed 5–7–13; 8:45 am]

BILLING CODE 4310–FB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCOS0600–L12200000–DU0000]

Notice of Proposed Supplementary Rules for Travel Management on Public Lands in Gunnison, Montrose, Hinsdale, and Saguache Counties, CO.

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Proposed Supplementary Rules.

SUMMARY: The Bureau of Land Management (BLM) Colorado is proposing supplementary rules for public lands included in the Gunnison Basin Federal Lands Travel Management Plan (TMP), approved on June 28, 2010. These proposed supplementary rules would apply to public lands administered by the BLM, Gunnison Field Office in Gunnison, Montrose, Hinsdale, and Saguache counties, Colorado. The proposed rules would implement decisions found in the TMP relating to the use of motorized and non-motorized vehicles.

DATES: You should submit your comments by July 8, 2013.

ADDRESSES: You may submit comments by the following methods: Mail or hand deliver to Kristi Murphy, Outdoor Recreation Planner, BLM Gunnison Field Office, 650 S. 11th Street, Gunnison, CO 81230. You may also submit comments via email to *kmurphy@blm.gov* (include ''Proposed Supplementary Rules'' in the subject line).

FOR FURTHER INFORMATION CONTACT: Kristi Murphy, Outdoor Recreation Planner, at BLM Gunnison Field Office, 650 S. 11th Street, Gunnison, Colorado 81230, or by phone at 970–642–4955. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 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:

I. Public Comment Procedures

Written comments on the proposed supplementary rules should be specific, be confined to issues pertinent to the proposed supplementary rules, and explain the reason for any recommended change. Where possible, comments should reference the specific section or paragraph of the proposed supplementary rules that the comment is addressing. The BLM is not obligated to consider or include in the Administrative Record for the final supplementary rules comments the BLM receives after the close of the comment period (see **DATES**), unless they are postmarked or electronically dated before the deadline, or comments delivered to an address other than one of the addresses listed above (see **ADDRESSES**).

Comments, including names, street addresses, and other contact information of respondents, will be available for public review at the address listed above, during regular business hours (7:30 a.m. to 4:30 p.m., Monday through Friday, except on Federal holidays). Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

II. Background

Before 2010, the BLM Gunnison Field Office used the BLM's 1980 Transportation Plan and the 2001 Gunnison Interim Travel Plan issued by the BLM and the U.S. Forest Service to manage travel on BLM-managed lands. As called for in the 2001 Travel Plan, the BLM and the Forest Service embarked on a planning process to develop a more definitive and comprehensive system of routes across Federal lands in the Gunnison Basin. The two agencies jointly published in the **Federal Register** a Notice of Intent to Prepare an Environmental Impact Statement at 72 FR 24267 (May 2, 2007). They subsequently published the Gunnison Basin Federal Lands Travel Management Plan (TMP) Environmental Impact Statement (EIS) (CO–160–2008–025–EIS). Following analysis of the public comments, the BLM issued a decision record on June 28, 2010. The TMP replaces the 1980 Transportation Plan and the 2001 Interim Travel Plan. These proposed supplementary rules would enable the BLM to implement several key decisions contained in the TMP to protect natural resources and provide for public health and safety. No other existing rules would be affected by these proposed supplementary rules.

III. Discussion of Proposed Supplementary Rules

These proposed supplementary rules apply to public lands administered by the BLM Gunnison Field Office. The TMP area consists of approximately 585,012 acres of public lands within Gunnison, Montrose, Hinsdale and Saguache counties, Colorado, in the following described townships:

Sixth Principal Meridian

Tps. 11 S., Rs. 83 and 84 W., unsurveyed.
Tps. 11 S., Rs. 86 and 87 W., partly unsurveyed.
Tps. 12 S., Rs. 82 to 87 W., partly unsurveyed.
Tps. 13 S., Rs. 80 to 87 W., partly unsurveyed.
Tps. 14 S., Rs. 80 to 88 W., partly unsurveyed.
Tps. 15 S., Rs. 81 to 88 W., partly unsurveyed.

New Mexico Principal Meridian

Tps. 43 N., Rs. 1 and 2 E., partly unsurveyed.
Tps. 44 N., Rs. 1, 2, and 3 E., partly unsurveyed.
Tps. 45 N., Rs. 1, 2, and 3 E., partly unsurveyed.
Tps. 46 N., Rs. 1 to 4 E., partly unsurveyed.
Tps. 47 N., Rs. 1 to 7 E., partly unsurveyed.
Tps. 48 N., Rs. 1 to 7 E.
Tps. 49 N., Rs. 1 to 6 E.
Tps. 50 N., Rs. 1 to 6 E.
Tps. 51 N., Rs. 1 to 5 E.
Tps. 41 N., Rs. 5 and 6 W., unsurveyed.
Tps. 42 N, Rs. 3 to 6 W., partly unsurveyed.
Tps. 43 N., Rs. 1 to 7 W., partly unsurveyed.
Tps. 44 N., Rs. 1 to 6 W., partly unsurveyed.
Tps. 45 N., Rs. 1 to 6 W., partly unsurveyed.
Tps. 46 N., Rs. 1 to 6 W., partly unsurveyed.
Tps. 47 N., Rs. 1 to 6 W.
Tps. 48 N., Rs. 1 to 6 W.
Tps. 49 N., Rs. 1 to 6 W.
Tps. 50 N., Rs. 1 to 4 W.
Tps. 51 N., Rs. 1 to 4 W.

The proposed supplementary rules are consistent with the decision record for the TMP, approved on June 28, 2010. The TMP includes specific management actions that restrict certain activities and define allowable uses. These proposed supplementary rules would apply only to public lands administered by the BLM Gunnison Field Office. The proposed supplementary rules would restrict the possession and use of mechanized and motorized vehicles to designated travel routes which were defined in the TMP. The proposed rules would provide two exemptions from the restrictions. One exemption would allow big game hunters to use game carts—which are considered mechanized vehicles—off of designated travel routes to retrieve large game animals outside of designated wilderness and wilderness study areas. Game carts would continue to be excluded from designated wilderness and wilderness study areas. The second exemption would allow vehicles to pull off of designated travel routes up to 30 feet from the edge of a roadway and to travel within 300 feet of a designated travel route on existing routes to accommodate parking, dispersed camping, and general recreation.

The proposed supplementary rules would also restrict the possession and use of motorized vehicles in priority sage-grouse habitat from March 15 to May 15. Restrictions on general travel and off-highway vehicle use are intended to enhance public safety, protect natural and cultural resources, eliminate motorized and non-motorized impacts on sensitive species habitat, and reduce conflicts among public land users.

IV. Procedural Matters

Executive Order 12866, Regulatory Planning and Review

These proposed supplementary rules are not a significant regulatory action and are not subject to review by Office of Management and Budget under Executive Order 12866. These proposed supplementary rules would not have an effect of $100 million or more on the economy. These proposed supplementary rules would not adversely affect in a material way the economy; productivity; competition; jobs; the environment; public health or safety; or state, local, or tribal governments or communities. These proposed supplementary rules would not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. These proposed supplementary rules do not materially alter the budgetary effects of entitlements, grants, user fees, or loan programs, or the rights or obligations of their recipients; nor do they raise novel legal or policy issues. These proposed supplementary rules would not affect legal commercial activity, but merely impose limitations on certain recreational activities on certain public lands to protect natural resources and human health and safety.

Clarity of the Supplementary Rules

Executive Order 12866 requires each agency to write regulations that are simple and easy to understand. In addition to written comments requested on substantive issues pertinent to the proposed supplementary rules, the BLM invites comments on how to make these proposed supplementary rules easier to understand, including answers to questions such as the following:

(1) Are the requirements in the proposed supplementary rules clearly stated?

(2) Do the proposed supplementary rules contain technical language or jargon that interferes with their clarity?

(3) Does the format of the proposed supplementary rules (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity?

(4) Would the proposed supplementary rules be easier to understand if they were divided into more (but shorter) sections?

(5) Is the description of the proposed supplementary rules in the ''Discussion of Proposed Supplementary Rules'' section of this preamble helpful in understanding these proposed supplementary rules? How could this description be more helpful in making the proposed supplementary rules easier to understand?

Please send any comments you have on the clarity of the proposed supplementary rules to the address specified in the **ADDRESSES** section.

National Environmental Policy Act

These proposed supplementary rules implement key decisions in the TMP. During the National Environmental Policy Act (NEPA) review for the TMP, the BLM fully analyzed the substance of these proposed supplementary rules in Environmental Impact Statement (EIS) (CO–160–2008–025–EIS). The BLM signed the Decision Record for the EIS on June 28, 2010. The BLM will place the TMP EIS, Decision Record and an appropriate Determination of NEPA Adequacy (DNA) on file in the BLM Administrative Record at the address specified in the **ADDRESSES** section.

Regulatory Flexibility Act

Congress enacted the Regulatory Flexibility Act of 1980 (RFA), as amended, 5 U.S.C. 601–612, to ensure that Government regulations do not unnecessarily or disproportionately burden small entities. The RFA requires a regulatory flexibility analysis if a rule would have a significant economic impact, either detrimental or beneficial, on a substantial number of small entities. These proposed supplementary rules would have no effect on business entities of any size. These proposed supplementary rules would merely impose reasonable restrictions on certain recreational activities on certain public lands to protect natural resources and the environment and human health and safety. Therefore, the BLM has determined under the RFA that these proposed supplementary rules would not have a significant economic impact on a substantial number of small entities.

Small Business Regulatory Enforcement Fairness Act

These proposed supplementary rules are not a ''major rule'' as defined at 5 U.S.C. 804(2). These proposed supplementary rules would merely impose reasonable restrictions on certain recreational activities on certain public lands to protect natural resources and the environment and human health and safety. These proposed supplementary rules would not:

(1) Have an annual effect on the economy of $100 million or more;

(2) Cause a major increase in costs or prices for consumers, individual industries, Federal, state, or local agencies, or geographic regions; or

(3) Have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Unfunded Mandates Reform Act

These proposed supplementary rules would not impose an unfunded mandate on state, local, or tribal governments, or the private sector of more than $100 million per year; nor would these proposed supplementary rules have a significant or unique effect on state, local, or tribal governments or the private sector. The proposed supplementary rules would merely impose reasonable restrictions on certain recreational activities on certain public lands to protect natural resources and the environment and human health and safety. Therefore, the BLM is not required to prepare a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*).

Executive Order 12630, Governmental Actions and Interference With Constitutionally Protected Property Rights (Takings)

These proposed supplementary rules do not constitute a Government action capable of interfering with constitutionally protected property rights. The proposed supplementary rules would not address property rights in any form, and would not cause the impairment of constitutionally protected property rights. Therefore, the BLM has determined that these proposed supplementary rules would not cause a ''taking'' of private property or require further discussion of takings implications under this Executive Order.

Executive Order 13132, Federalism

The proposed supplementary rules would not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, the BLM has determined that these proposed supplementary rules do not have sufficient Federalism implications to warrant preparation of a Federalism Assessment.

Executive Order 12988, Civil Justice Reform

Under Executive Order 12988, the BLM Colorado State Director has determined that these proposed supplementary rules would not unduly burden the judicial system and that they meet the requirements of Sections 3(a) and 3(b) (2) of the Order.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, the BLM has found that these proposed rules do not include policies that have tribal implications, and would have no bearing on trust lands or on lands for which title is held in fee status by Indian tribes or U.S. Government-owned lands managed by the Bureau of Indian Affairs.

Information Quality Act

In developing these proposed supplementary rules, the BLM did not conduct or use a study, experiment or survey requiring peer review under the Information Quality Act (Section 515 of Pub. L. 106–554).

Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

These proposed supplementary rules do not comprise a significant energy action. These proposed supplementary rules would not have an adverse effect on energy supply, production, or

consumption and have no connection with energy policy.

Executive Order 13352, Facilitation of Cooperative Conservation

In accordance with Executive Order 13352, the BLM has determined that the proposed supplementary rules would not impede facilitating cooperative conservation; would take appropriate account of and consider the interests of persons with ownership or other legally recognized interests in land or other natural resources; would properly accommodate local participation in the Federal decision-making process; and would provide that the programs, projects, and activities are consistent with protecting public health and safety.

Paperwork Reduction Act

These proposed supplementary rules do not contain information collection requirements that the Office of Management and Budget must approve under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521.

Author

The principal author of these proposed supplementary rules is Kristi Murphy, Outdoor Recreation Planner, BLM, Gunnison Field Office.

V. Proposed Rules

For the reasons stated in the Preamble, and under the authority of 43 U.S.C. 315a, 1733(a), and 1740, and 43 CFR 8365.1–6, the State Director proposes supplementary rules for public lands within the Gunnison Field Office, Colorado, to read as follows:

Supplementary Rules for the Gunnison Basin Travel Management Plan Area

Definitions

Camping means erecting a tent or a shelter of natural or synthetic materials, preparing a sleeping bag or other bedding material for use, or parking a motor vehicle, motor home, or trailer for the purpose or apparent purpose of overnight occupancy.

Designated travel routes means roads and trails open to specified modes of travel and identified on a map of designated roads and trails that is maintained and available for public inspection at the Bureau of Land Management (BLM) Gunnison Field Office, Colorado. Designated roads and trails are open to public use in accordance with such limits and restrictions as are, or may be, specified in the resource management plan (RMP) or travel management plan (TMP), or in future decisions implementing the RMP. This definition excludes any road or trail with BLM-authorized restrictions that prevent use of the road or trail. Restrictions may include signs or physical barriers such as gates, fences, posts, branches, or rocks.

Existing travel routes means immediately recognizable motor vehicle travel routes or two-track trails that are not identified as closed to motorized vehicle use by a BLM sign or map.

Public land means any land or interest in land owned by the United States and administered by the Secretary of the Interior through the BLM without regard to how the United States acquired ownership.

Mechanized vehicle means a human-powered mechanical device, such as a bicycle; not powered by a motor.

Motorized vehicle means a vehicle that is propelled by a motor or engine, such as a car, truck, off-highway vehicle, motorcycle, or snowmobile.

Prohibited Acts

1. Except as provided by Rule 2 below, you must not operate or possess a motorized or mechanized vehicle in an area designated as closed to such use by a BLM sign or map.

2. You must not operate or possess a mechanized or motorized vehicle except in areas designated or routes identified for such use by a BLM sign or map, unless:

- You are using a mechanized game cart for the purpose of retrieving a large game animal outside of Congressionally designated wilderness areas or wilderness study areas; or
- You are using a motorized vehicle for the purpose of parking or camping within 30 feet of the edge of a designated travel route or on existing travel routes within 300 feet of a designated travel route.

3. You must not operate or possess a motorized vehicle from March 15 to May 15 in specific areas of priority sage-grouse habitat as designated by a BLM sign or map, except to access private inholdings with proper authorization.

Exceptions

These supplementary rules do not apply to emergency, law enforcement, and Federal or other government vehicles while being used for official or other emergency purposes, or to any other vehicle use that is expressly authorized or otherwise officially approved by the BLM.

Penalties

Under Section 303(a) of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1733(a) and 43 CFR 8360.0–7), any person who violates any of these supplementary rules may be tried before a United States Magistrate and fined no more than $1,000 or imprisoned for no more than 12 months, or both. Such violations may also be subject to the enhanced fines provided for by 18 U.S.C. 3571.

Helen M. Hankins,

Bureau of Land Management, Colorado State Director.

[FR Doc. 2013–10896 Filed 5–7–13; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–PWR–PWRO–12638; PPPWGOGAY0 PPMPSAS1Z.YP0000]

Vista Grande Drainage Basin Improvement Project, Fort Funston, Golden Gate National Recreation Area, San Francisco County, CA

AGENCY: National Park Service, Interior.

ACTION: Notice of Intent to Prepare an Environmental Impact Statement.

SUMMARY: In accordance with § 102(2)(C) of the National Environmental Policy Act (NEPA), and the California Environmental Quality Act (CEQA) Guidelines Section 15082, the National Park Service, together with the City of Daly City, intends to prepare a joint Environmental Impact Statement (EIS) and Environmental Impact Report (EIR) to evaluate the potential environmental effects of the proposed Vista Grande Drainage Basin Improvement Project (Project). The EIS/EIR will address proposed improvements to Daly City's infrastructure to address storm-related flooding in the Vista Grande Watershed Drainage Basin and the effects of coastal erosion. The National Park Service (NPS) is the lead agency for the environmental review under NEPA. The City of Daly City is the lead agency for the environmental review under CEQA.

DATES: All written comments must be postmarked not later than June 7, 2013.

Background: The Vista Grande watershed area is located in the City of Daly City and unincorporated Broadmoor Village, in northwestern San Mateo County. This watershed is approximately 2.5 square miles in area and is bordered by San Francisco County to the north, Colma Creek watershed to the south and east, and the Pacific Ocean on the west. The Vista Grande watershed is drained through the Vista Grande Canal and Tunnel, which are located in the City and County of San Francisco, adjacent to John Muir Drive and the southwestern shoreline of Lake Merced. The Vista

Grande Tunnel is a sub-surface tunnel beneath Fort Funston, which is owned and managed by NPS as part of the Golden Gate National Recreation Area (GGNRA). The Vista Grande Tunnel connects the Vista Grande watershed to an outfall located on the beach below the Fort Funston bluffs, through which stormwater flows are discharged into the Pacific Ocean.

The City of Daly City has proposed the Project to address storm-related flooding in the Vista Grande Watershed Drainage Basin. The existing Vista Grande Canal and Tunnel do not have adequate hydraulic capacity to convey peak storm flows. As a result, during storm events, flooding periodically occurs in adjacent low-lying residential areas and along John Muir Drive. The Project would involve upgrades to the Vista Grande watershed collection system upstream of the Vista Grande Canal; partial replacement of the existing Vista Grande Canal to incorporate a gross-solid screening device, a treatment wetland, and diversion and discharge structures to route some stormwater (and authorized non-storm water) flows from the Vista Grande Canal to Lake Merced; replacement of the existing Vista Grande Tunnel to expand its capacity; and replacement of the existing outfall structure at Fort Funston.

SUPPLEMENTARY INFORMATION: Along with evaluating a No-Action Alternative, the EIS/EIR will consider a range of alternatives, including various combinations of facilities, such as alternative tunnel alignments and capacities, storm water detention structures, lake level scenarios, and groundwater recharge facilities. The Project would increase the hydraulic capacity of the canal and tunnel and extend its operating life. In addition, the Project would utilize stormwater to restore the level of Lake Merced, which declined in the late-1980s and early-1990s and has not fully recovered. Under the Project, an adjustable-height weir would be used to control the lake level and allow water to be diverted back into the Vista Grande Canal.

The existing outfall, a segment of the Vista Grande Tunnel, and the force main segment are presently exposed to the surf and waves, which have caused significant damage to the structure. The Project would reconfigure these structures to provide protection from the surf and waves. The existing Daly City outfall structure would be removed and replaced with a low-profile outfall structure set into the existing cliff face to reduce future erosion. The existing force main would also be removed and replaced with a similar configuration set back into the cliff face. The existing submarine outfall pipeline and diffuser would be renovated to protect it from erosion and extend its operating life.

FOR FURTHER INFORMATION CONTACT: Steve Ortega, Golden Gate NRA, Fort Mason, Building 201, San Francisco, CA 94123; telephone (415) 561–2841 or email *goga_planning@nps.gov.*

Public Scoping and Comment: Notice is hereby given that a public scoping process and comment phase has been initiated for the EIS/EIR. The purpose of the public scoping process is to elicit public comment regarding the full spectrum of issues and concerns, a suitable range of alternatives, the nature and extent of potential environmental impacts or ecological benefits, and appropriate mitigation strategies that should be addressed in preparing a draft EIS/EIR. Preliminary issues to be addressed in the EIS/EIR include habitat for fish and wildlife, ecosystem conditions and processes, effects on special status plant and animal species, hydrology, flood hazards, traffic, air quality, visitor access, and visitor experience. Public scoping meetings will be scheduled in San Francisco and San Mateo Counties. Meeting dates, times, and locations will be publicized through local and regional news media, by email to the park mailing list (to be included on the Project email list, please visit: *http://ww.nps.gov/goga* and click the ''Join the Mailing List'' link), and via the Project Web site: *http://parkplanning.nps.gov/Vista_Grande.* This Project Web site will also provide relevant information, including the Project description, planning process updates, meeting notices, reports and documents, and useful links associated with the Project.

All written comments should be mailed to the following address: Superintendent, Golden Gate National Recreation Area; Attn: Vista Grande Project; Fort Mason, Building 201, San Francisco, CA 94123. 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.

Decision Process: At this time, it is anticipated that the draft EIR/EIS will be distributed for public review in late 2013. Availability of the document for review will be announced by the publication of a Notice of Availability in the **Federal Register**, through local and regional news media, via the Project Web site, and by email to Project email recipients. Additional public meetings will be held, and further opportunities for public comment will be provided, after the draft EIS/EIR is distributed. Following due consideration of all comments received on the draft EIS/EIR, preparation of the final document is anticipated to be completed in 2014. Because this is a delegated EIS, the official responsible for approval of the Project is the Regional Director, Pacific West Region. Subsequently the official responsible for implementation of the approved Project is the Superintendent, Golden Gate National Recreation Area.

Dated: March 15, 2013.

Christine S. Lehnertz,

Regional Director, Pacific West Region.

[FR Doc. 2013–10914 Filed 5–7–13; 8:45 am]

BILLING CODE 4312–FF–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Well-being Supplement to the American Time Use Survey

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Bureau of Labor Statistics (BLS) sponsored information collection request (ICR) titled, ''Well-being Supplement to the American Time Use Survey,'' to the Office of Management and Budget (OMB) for review and approval for continued use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 et seq.).

DATES: Submit comments on or before June 7, 2013.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site, *http://www.reginfo.gov/public/do/PRAMain*, on the day following publication of this notice or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk

Officer for DOL–BLS, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503, Fax: 202–395–6881 (this is not a toll-free number), email: *OIRA_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: The American Time Use Survey (ATUS) Well-being supplement includes questions about how people experience their time. For example, the supplement asks how happy and stressed the respondent was the day before and the degree to which they felt pain. The supplement also includes questions on general health and life satisfaction. Information collected in the Well-being module is published as a public use data set to facilitate research on numerous topics, such as how people experience time spent in different activities, times of social interaction, and pain; the relationship between health and time use; and the relationship between life satisfaction and point-in-time affective experiences. Sponsored by the National Institute of Aging (NIA) of the National Institutes of Health, the module is asked of all respondents immediately upon their completion of the ATUS. The Well-being module supports the BLS mission, by providing new insight into the ATUS data on time use and information specifically about workers' affective experiences. The data collection supports the NIA mission, by providing information about the health and well-being of older Americans.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1220–0182. The current approval is scheduled to expire on June 30, 2013; however, it should be noted that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional information, see the related notice published in the **Federal Register** on January 11, 2013 (78 FR 2446).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1220–0185. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–BLS.

Title of Collection: Well-being Supplement to the American Time Use Survey.

OMB Control Number: 1220–0185.

Affected Public: Individuals or households.

Total Estimated Number of Respondents: 12,800.

Total Estimated Number of Responses: 12,800.

Total Estimated Annual Burden Hours: 1,067.

Total Estimated Annual Other Costs Burden: $0.

Dated: May 1, 2013.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2013–10868 Filed 5–7–13; 8:45 am]

BILLING CODE 4510–24–P

LEGAL SERVICES CORPORATION

Sunshine Act Meetings

ACTION: Notice.

DATE AND TIME: The Legal Services Corporation's Institutional Advancement Committee will meet telephonically on May 14, 2013. The meeting will commence at 4:00 p.m., EDT, and will continue until the conclusion of the Committee's agenda.

LOCATION: John N. Erlenborn Conference Room, Legal Services Corporation Headquarters, 3333 K Street NW., Washington, DC 20007.

PUBLIC OBSERVATION: Members of the public who are unable to attend in person but wish to listen to the public proceedings may do so by following the telephone call-in directions provided below.

CALL-IN DIRECTIONS FOR OPEN SESSIONS:

- Call toll-free number: 1–866–451–4981;
- When prompted, enter the following numeric pass code: 5907707348;
- When connected to the call, please immediately ''MUTE'' your telephone.

Members of the public are asked to keep their telephones muted to eliminate background noises. To avoid disrupting the meeting, please refrain from placing the call on hold if doing so will trigger recorded music or other sound. From time to time, the presiding Chair may solicit comments from the public.

STATUS OF MEETING: Open, except that, upon a vote of the Board of Directors, the meeting may be closed to the public to discuss prospective funders for LSC's development activities and 40th anniversary celebration.

A verbatim written transcript will be made of the closed session meeting of the Institutional Advancement Committee. The transcript of any portion of the closed session falling within the relevant provisions of the Government in the Sunshine Act, 5 U.S.C. 552b(c)(6) and (9) will not be available for public inspection. A copy of the General Counsel's Certification that, in his opinion, the closing is authorized by law will be available upon request.

MATTERS TO BE CONSIDERED:

OPEN

1. Approval of agenda
2. Discussion of proposed timeline for LSC's 40th anniversary celebration planning
3. Public comment
4. Consider and act on other business

CLOSED

5. Discussion of prospective funders for LSC's development activities and 40th anniversary celebration
6. Consider and act on adjournment of meeting.

CONTACT PERSON FOR INFORMATION: Katherine Ward, Executive Assistant to

the Vice President & General Counsel, at (202) 295–1500. Questions may be sent by electronic mail to *FR_NOTICE_QUESTIONS@lsc.gov.*

ACCESSIBILITY: LSC complies with the Americans with Disabilities Act and Section 504 of the 1973 Rehabilitation Act. Upon request, meeting notices and materials will be made available in alternative formats to accommodate individuals with disabilities. Individuals who need other accommodations due to disability in order to attend the meeting in person or telephonically should contact Katherine Ward, at (202) 295–1500 or *FR_NOTICE_QUESTIONS@lsc.gov,* at least 2 business days in advance of the meeting. If a request is made without advance notice, LSC will make every effort to accommodate the request but cannot guarantee that all requests can be fulfilled.

Dated: May 6, 2013.

Atitaya C. Rok,

Staff Attorney.

[FR Doc. 2013–11069 Filed 5–6–13; 4:15 pm]

BILLING CODE 7050–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2012–0180]

Adequacy of Design Features and Functional Capabilities Identified and Described for Withstanding Aircraft Impacts

AGENCY: Nuclear Regulatory Commission.

ACTION: Standard review plan section; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing a new section of NUREG–0800, ''Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition.'' The new section, designated as Revision 0, is Section 19.5, ''Adequacy of design features and functional capabilities identified and described for withstanding aircraft impacts.''

DATES: The effective date of this Standard Review Plan (SRP) update is June 7, 2013.

ADDRESSES: Please refer to Docket ID NRC–2012–0180 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and is publicly available, by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0180. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly-available documents online in the NRC Library 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 notice (if that document is available in ADAMS) is provided the first time that a document is referenced. Final Revision 0 to NUREG–0800 is available in ADAMS under Accession No. ML12276A112.
- *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.
- The NRC posts its issued staff guidance on the NRC's external Web page (*http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/*).

FOR FURTHER INFORMATION CONTACT: Ms. Anna H. Bradford, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–1560, email: *Anna.Bradford@nrc.gov.*

SUPPLEMENTARY INFORMATION: On August 2, 2012 (77 FR 46128), the NRC published for public comment the proposed Revision 0 to Section 19.5, ''Adequacy of design features and functional capabilities identified and described for withstanding aircraft impacts,'' (ADAMS Accession No. ML12138A468). Three comment submissions were received on the proposed revision (ADAMS Accession Nos.: ML12249A406, ML12237A139 and ML12258A071). The staff made changes to the proposed revision after consideration of the comments. A summary of the comments and the staff's disposition of the comments are available in a separate document, *Response to Public Comments On Draft Standard Review Plan (SRP) 19.5: Adequacy Of Design Features And Functional Capabilities Identified And Described For Withstanding Aircraft Impacts* (ADAMS Accession No. ML12306A341). The staff has also prepared a redline version of the SRP section showing the difference between the proposed and final SRP section (ADAMS Accession No. ML12307A168).

The NRC staff will incorporate the positions reflected in Revision 0 of SRP Section 19.5 into the next revision of Regulatory Guide 1.206, ''Combined License Applications for Nuclear Power Plants'' (ADAMS Accession No. ML070720184).

Backfitting and Issue Finality

Issuance of this final SRP section does not constitute backfitting as defined in § 50.109 of Title 10 of the *Code of Federal Regulations* (10 CFR) (the Backfit Rule) and is not otherwise inconsistent with the issue finality provisions in part 52 of 10 CFR. The staff's position is based upon the following considerations:

- The SRP positions do not constitute backfitting, inasmuch as the SRP is internal guidance directed at the NRC staff with respect to their regulatory responsibilities.
- The SRP positions represent the first internal NRC guidance on a regulation for which the backfitting and issue finality considerations have already been addressed.
- The NRC staff has no intention to impose the SRP positions on current licensees and regulatory approvals either now or in the future.
- Backfitting and issue finality do not—with limited exceptions not applicable here—protect current or future applicants.

Each of these considerations is discussed in more detail below.

1. *The SRP positions do not constitute backfitting, inasmuch as the SRP is internal guidance directed at the NRC staff with respect to their regulatory responsibilities.*

The SRP provides guidance to the staff on how to review an application for NRC regulatory approval in the form of licensing. Changes in internal staff guidance are not matters for which either nuclear power plant applicants or licensees are protected under either the Backfit Rule or the issue finality provisions of part 52.

2. *The SRP positions represent the first internal NRC guidance on a regulation for which the backfitting and issue finality considerations have already been addressed.*

This SRP addresses compliance with the Aircraft Impact Assessment (AIA) Rule, 10 CFR 50.150. The backfitting and issue finality issues for this rulemaking were addressed as part of the original AIA rulemaking (74 FR 28112, 28143–45; June 12, 2009).

Inasmuch as the SRP merely implements the AIA Rule, the SRP introduces no new backfitting or issue finality matters apart from those addressed in the underlying rulemaking. Therefore, the staff's position is that the NRC's consideration of backfitting and issue finality matters for the underlying AIA rulemaking also serves as the NRC's consideration of the same backfitting and issue finality matters for the issuance of this SRP.

3. *The NRC staff has no intention to impose the SRP positions on current licensees and regulatory approvals either now or in the future.*

The staff does not intend to impose or apply the positions described in the SRP to existing (already issued) licenses and regulatory approvals. Hence, the issuance of a final SRP—even if considered guidance which is within the purview of the issue finality provisions in part 52—need not be evaluated as if it were a backfit or as being inconsistent with issue finality provisions. If, in the future, the staff seeks to impose a position in the SRP on holders of already issued holders of licenses SRP in a manner which does not provide issue finality as described in the applicable issue finality provision, then the staff must make the showing as set forth in the Backfit Rule or address the criteria for avoiding issue finality as described applicable issue finality provision.

4. *Backfitting and issue finality do not—with limited exceptions not applicable here—protect current or future applicants.*

Applicants and potential applicants are not, with certain exceptions, protected by either the Backfit Rule or any issue finality provisions under part 52. This is because neither the Backfit Rule nor the issue finality provisions under part 52—with certain exclusions discussed below—were intended to apply to every NRC action which substantially changes the expectations of current and future applicants.

The exceptions to the general principle are applicable whenever an applicant references a part 52 license (e.g., an early site permit) and/or NRC regulatory approval (e.g., a design certification rule) with specified issue finality provisions. The staff does not, at this time, intend to impose the positions represented in the SRP in a manner that is inconsistent with any issue finality provisions. If, in the future, the staff seeks to impose a position in the SRP in a manner which does not provide issue finality as described in the applicable issue finality provision, then the staff must address the criteria for avoiding issue finality as described in the applicable issue finality provision.

Congressional Review Act

In accordance with the Congressional Review Act, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of the Office of Management and Budget.

Dated at Rockville, Maryland, this 25th day of April 2013.

For the Nuclear Regulatory Commission.

Anna Bradford,

Acting Chief, Policy Branch, Division of Advanced Reactors and Rulemaking, Office of New Reactors.

[FR Doc. 2013–10920 Filed 5–7–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–264; NRC–2012–0026]

Dow Chemical Company, Dow TRIGA Research Reactor; License Renewal for the Dow Chemical TRIGA Research Reactor; Supplemental Information and Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; supplemental information and correction.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) published a notice in the **Federal Register** on July 20, 2012 (77 FR 42771), ''License Renewal for the Dow Chemical TRIGA Research Reactor,'' to inform the public that the NRC is considering issuance of a renewed Facility License No. R–108 for Dow Chemical Company which would authorize continued operation of the Dow TRIGA Research Reactor. The notice provided the NRC staff's review of the Environmental Assessment and Finding of No Significant Impact for the Dow TRIGA Research Reactor. This action is necessary to (1) correct a typographical error in Section II.A., ''Radiological Impact;'' and (2) provide the public with supplemental information regarding the U.S. Court of Appeals Waste Confidence Ruling and NRC staff review of the ruling showing the non-applicability to research and test reactor licensing.

ADDRESSES: Please refer to Docket ID NRC–2012–0026 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and is publicly available, using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0026. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library 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.*
- *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: Geoffrey A. Wertz, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone 301–415–0893, email: *Geoffrey.Wertz@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Correction

In the **Federal Register** (FR) of July 20, 2012, in FR Doc. 2012–17733, on page 42772, in the second column, first paragraph, second line, replace ''retains'' with ''takes.''

II. Supplemental Information

On June 8, 2012, the U.S. Court of Appeals for the District of Columbia Circuit found that some aspects of the 2010 Waste Confidence Rulemaking did not satisfy the NRC's National Environmental Policy Act obligations and vacated the rulemaking. On August 7, 2012, the Commission directed the NRC staff not to issue any licenses dependent on the Waste Confidence Rule until the court's remand has been appropriately addressed. The NRC staff analyzed the Waste Confidence Rule (part 51.23 of Title 10 of the *Code of Federal* Regulations (10 CFR), ''Temporary Storage of Spent Fuel after Cessation of Reactor Operation-Generic Determination of No Significant Environmental Impact''), as well as supplemental information, and concluded that 10 CFR 51.23 does not specifically refer to research and test reactors (RTRs), only to power reactors and independent spent fuel storage

installations. As such, RTR licensing does not rely or depend on the Waste Confidence Rule. The NRC staff's memo documenting this review can be found in the NRC's Agencywide Documents Access and Management System under Accession No. ML13071A642.

Dated at Rockville, Maryland, this 1st day of May 2013.

For the Nuclear Regulatory Commission.

Alexander Adams, Jr.,

Chief, Research and Test Reactors Licensing Branch, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.

[FR Doc. 2013–10927 Filed 5–7–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–326; NRC–2010–0217]

University of California, Irvine; License Renewal for University of California, Irvine Nuclear Reactor Facility; Supplemental Information

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; supplemental information.

SUMMARY: The Nuclear Regulatory Commission (NRC) published a notice in the **Federal Register** on February 13, 2012 (77 FR 7610–7613), ''Notice of Availability of Environmental Assessment and Finding of No Significant Impact for the License Renewal for University of California, Irvine Nuclear Reactor Facility,'' to inform the public that the NRC is considering issuance of a renewed Facility License No. R–116 for the Regents of the University of California (the licensee) which would authorize continued operation of the University of California, Irvine Nuclear Reactor Facility. The notice provided the NRC staff's review of the Environmental Assessment and Finding of No Significant Impact for the University of California, Irvine Nuclear Reactor Facility. This action is necessary to provide the public with supplemental information regarding the U.S. Court of Appeals Waste Confidence Ruling and NRC staff review of the ruling showing the non-applicability to research and test reactor licensing.

ADDRESSES: Please refer to Docket ID NRC–2010–0217 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and is publicly available, using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2010–0217. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library 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.
- *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: Jason A. Lising, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone 301–415–3841, email: *Jason.Lising@nrc.gov.*

SUPPLEMENTARY INFORMATION: On June 8, 2012, the U.S. Court of Appeals for the District of Columbia Circuit found that some aspects of the 2010 Waste Confidence Rulemaking did not satisfy the NRC's National Environmental Policy Act obligations and vacated the rulemaking. On August 7, 2012, the Commission directed the NRC staff not to issue any licenses dependent on the Waste Confidence Rule until the court's remand has been appropriately addressed. NRC staff analyzed the Waste Confidence Rule (part 51.23 of Title 10 of the *Code of Federal* Regulations (10 CFR), ''Temporary Storage of Spent Fuel after Cessation of Reactor Operation-Generic Determination of No Significant Environmental Impact,'') as well as supplemental information, and concluded that 10 CFR 51.23 does not specifically refer to research and test reactors (RTRs), only to power reactors and independent spent fuel storage installations. As such, RTR licensing does not rely or depend on the Waste Confidence Rule. The NRC staff's memo documenting this review can be found in the NRC Agencywide Documents Access and Management System under Accession No. ML13071A642.

Dated at Rockville, Maryland, this 1st day of May, 2013.

For the Nuclear Regulatory Commission.

Alexander Adams, Jr.,

Chief, Research and Test Reactors Licensing Branch, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.

[FR Doc. 2013–10925 Filed 5–7–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Request To Amend a License To Export Radioactive Waste

Pursuant to 10 CFR 110.70 (b) ''Public Notice of Receipt of an Application,'' please take notice that the Nuclear Regulatory Commission (NRC) has received the following request for an export license amendment. Copies of the request are available electronically through ADAMS and can be accessed through the Public Electronic Reading Room (PERR) link *http://www.nrc.gov/reading-rm.html* at the NRC Homepage.

A request for a hearing or petition for leave to intervene may be filed within thirty days after publication of this notice in the **Federal Register**. Any request for hearing or petition for leave to intervene shall be served by the requestor or petitioner upon the applicant, the office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555; the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555; and the Executive Secretary, U.S. Department of State, Washington, DC 20520.

A request for a hearing or petition for leave to intervene may be filed with the NRC electronically in accordance with NRC's E-Filing rule promulgated in August 2007, 72 FR 49139 (Aug. 28, 2007). Information about filing electronically is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* To ensure timely electronic filing, at least 5 (five) days prior to the filing deadline, the petitioner/requestor should contact the Office of the Secretary by email at *HEARINGDOCKET@NRC.GOV,* or by calling (301) 415–1677, to request a digital ID certificate and allow for the creation of an electronic docket.

In addition to a request for hearing or petition for leave to intervene, written comments, in accordance with 10 CFR 110.81, should be submitted within thirty (30) days after publication of this notice in the **Federal Register** to Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Rulemaking and Adjudications.

The information concerning this export license amendment application follows.

NRC EXPORT LICENSE AMENDMENT APPLICATION

Description of Material

Name of applicant Date of application Date received Application No. Docket No.	Material type	Total quantity	End use	Country of destination
Perma-Fix Northwest. Inc.; April 15, 2013; April 23, 2013; XW012/03; 11005699.	No change in material (Class A radioactive waste).	No increase (up to a maximum total of 5,500 tons of low-level waste).	Amend to add two additional Atomic Energy of Canada Limited facilities as ''Ultimate Foreign Consignee(s).'' No other changes to the existing license which authorizes the export of non-conforming waste and/or waste resulting from processing materials imported under IW022 (and subsequent amendments).	Canada.

Dated this 29th day of April 2013 at Rockville, Maryland.

For the Nuclear Regulatory Commission.

Mark R. Shaffer,

Deputy Director, Office of International Programs.

[FR Doc. 2013–10916 Filed 5–7–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Request To Amend a License To Import Radioactive Waste

Pursuant to 10 CFR 110.70 (b) ''Public Notice of Receipt of an Application,'' please take notice that the Nuclear Regulatory Commission (NRC) has received the following request for an import license amendment. Copies of the request are available electronically through ADAMS and can be accessed through the Public Electronic Reading Room (PERR) link *http://www.nrc.gov/reading-rm.html* at the NRC Homepage.

A request for a hearing or petition for leave to intervene may be filed within thirty days after publication of this notice in the **Federal Register**. Any request for hearing or petition for leave to intervene shall be served by the requestor or petitioner upon the applicant, the office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555; the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555; and the Executive Secretary, U.S. Department of State, Washington, DC 20520.

A request for a hearing or petition for leave to intervene may be filed with the NRC electronically in accordance with NRC's E-Filing rule promulgated in August 2007, 72 FR 49139 (Aug. 28, 2007). Information about filing electronically is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html*. To ensure timely electronic filing, at least 5 (five) days prior to the filing deadline, the petitioner/requestor should contact the Office of the Secretary by email at *HEARINGDOCKET@NRC.GOV,* or by calling (301) 415–1677, to request a digital ID certificate and allow for the creation of an electronic docket.

In addition to a request for hearing or petition for leave to intervene, written comments, in accordance with 10 CFR 110.81, should be submitted within thirty (30) days after publication of this notice in the **Federal Register** to Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Rulemaking and Adjudications.

The information concerning this import license amendment application follows.

NRC IMPORT LICENSE AMENDMENT APPLICATION

[Description of Material]

Name of applicant Date of application Date received Application No. Docket No.	Material type	Total quantity	End use	Country from
Perma-Fix Northwest, Inc., April 15, 2013, April 23, 2013, IW022/03, 11005700.	No change in material (Class A radioactive waste).	No increase (up to a maximum total of 5,500 tons of low-level waste).	Amend to: (1) Change the licensee name from ''Perma-Fix Environmental Services, Inc.'' to ''Perma-Fix Northwest, Inc.'', and (2) add two additional Atomic Energy of Canada Limited facilities to ''Ultimate Foreign Consignee(s).'' No other changes to the existing license which authorizes the import of low-level waste for recycling and processing for volume reduction. The attributed Canadian waste will be returned under XW012 (and subsequent amendments).	Canada.

Dated this 29th day of April 2013 at Rockville, Maryland.

For the Nuclear Regulatory Commission.

Mark R. Shaffer,

Deputy Director, Office of International Programs.

[FR Doc. 2013–10917 Filed 5–7–13; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 30503; 812–13886]

Millington Exchange Traded MAVINS Fund, LLC and Millington Securities, Inc.; Notice of Application

May 2, 2013.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and (a)(2) of the Act.

APPLICANTS: Millington Exchange Traded MAVINS Fund, LLC (the ''Company'') and Millington Securities, Inc. (the ''Adviser'').

SUMMARY OF APPLICATION: Applicants request an order that permits: (a) Series of certain open-end management investment companies to issue shares (''Shares'') redeemable in large aggregations only (''Creation Units''); (b) secondary market transactions in Shares to occur at negotiated market prices; (c) certain series to pay redemption proceeds, under certain circumstances, more than seven days from the tender of Shares for redemption; and (d) certain affiliated persons of the series to deposit securities into, and receive securities from, the series in connection with the purchase and redemption of Creation Units.

DATES: *Filing Dates:* The application was filed on April 6, 2011, and amended on September 23, 2011, June 22, 2012, November 16, 2012, and May 1, 2013.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on May 28, 2013, and should be accompanied by proof of service on applicants, 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 Commission's Secretary.

ADDRESSES: Elizabeth M. Murphy, Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants: 222 South Mill Street, Naperville, IL 60540.

FOR FURTHER INFORMATION CONTACT: Jennifer L. Sawin, Branch Chief, at (202) 551–6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Company, a limited liability company organized under the laws of Delaware, intends to register with the Commission as an open-end management investment company. The Applicants are requesting relief not only for the Company and its current series, the Millington Large-Cap ETF (''Initial Fund''), but also with respect to future series of the Company, and to any registered open-end management investment companies or series thereof that may be created in the future and that utilizes active management investment strategies (''Future Funds'' and collectively with the Initial Fund, the ''Funds'').[1] Funds may invest in equity securities or fixed income securities traded in the U.S. or non-U.S. markets or a combination of equity and fixed income securities, including ''to-be-announced transactions'' (''TBAs'')[2] and depositary receipts (''Depositary Receipts'').[3] The securities, other assets, and other positions in which a Fund invests are its ''Portfolio Positions.''[4] The Company currently expects that the Initial Fund's investment objective will be to provide the potential for capital appreciation by investing in a portfolio of large-cap domestic equity securities.

2. Each Fund will (a) be advised by Millington Securities, Inc. or an entity controlling, controlled by or under common control with Millington Securities, Inc. (each such entity and any successor thereto included in the term ''Adviser'') and (b) comply with the terms and conditions stated in the application. Millington Securities, Inc. is an Illinois corporation and is registered as an investment adviser under section 203 of the Investment Advisers Act of 1940 (the ''Advisers Act''). Any other Adviser to a Fund will be registered under the Advisers Act. The Adviser may retain sub-advisers (each, a ''Fund Sub-Adviser'') in connection with the Funds; each Fund Sub-Adviser will be registered under the Advisers Act or not subject to such registration.

3. Millington Securities, Inc. is also a broker-dealer registered under the Securities Exchange Act of 1934 (''Exchange Act'') and either it or another broker-dealer registered under the Exchange Act will serve as the principal underwriter and distributor for each of the Funds (the ''Distributor''). No Distributor, Adviser, Fund Sub-Adviser, Fund or the Company will be an Affiliate of a Fund's Listing Exchange.

[1] All entities that currently intend to rely on the requested order are named as Applicants and any Fund that currently intends to rely on the requested order is identified in the application. Any other entity that relies on the requested order in the future will comply with the terms and conditions of the application.

[2] A TBA Transaction is a method of trading mortgage-backed securities. In a TBA Transaction, the buyer and seller agree on general trade parameters such as agency, settlement date, par amount and price. The actual pools delivered generally are determined two days prior to the settlement date.

[3] Depositary Receipts include American Depositary Receipts (''ADRs'') and Global Depositary Receipts (''GDRs''). With respect to ADRs, the depositary is typically a U.S. financial institution and the underlying securities are issued by a foreign issuer. The ADR is registered under the Securities Act of 1933 (''Securities Act'') on Form F–6. ADR trades occur either on a national securities exchange as defined in Section 2(a)(26) of the Act (''Listing Exchange'') or off-exchange. Financial Industry Regulatory Authority Rule 6620 requires all off-exchange transactions in ADRs to be reported within 90 seconds and ADR trade reports to be disseminated on a real-time basis. With respect to GDRs, the depositary may be a foreign or a U.S. entity, and the underlying securities may have a foreign or a U.S. issuer. All GDRs are sponsored and trade on a foreign exchange. No affiliated persons of Applicants, any Adviser, Fund Sub-Adviser (as defined below), or Fund will serve as the depositary for any Depositary Receipts held by a Fund. A Fund will not invest in any Depositary Receipts that the Adviser (or, if applicable, the Fund Sub-Adviser) deems to be illiquid or for which pricing information is not readily available.

[4] If a Fund invests in derivatives: (a) The Board periodically will review and approve (i) the Fund's use of derivatives and (ii) how the Fund's investment adviser assesses and manages risk with respect to the Fund's use of derivatives; and (b) the Fund's disclosure of its use of derivatives in its offering documents and periodic reports will be consistent with relevant Commission and staff guidance.

4. Shares of each Fund will be purchased from the Company only in large aggregations of a specified number referred to as ''Creation Units.'' Creation Units may be purchased through orders placed with the Distributor by or through an ''Authorized Participant'' which is either (1) a broker-dealer or other participant in the Continuous Net Settlement (''CNS'') System of the National Securities Clearing Corporation (''NSCC''), a clearing agency that is registered with the Commission, or (2) a participant (''DTC Participant'') in the Depository Trust Company ''DTC''), and which in either case has executed a participant agreement with the Distributor, the Fund, and the Fund's transfer agent with respect to the creation and redemption of Creation Units. Purchases and redemptions of the Funds' Creation Units will be processed either through an enhanced clearing process available to DTC Participants that are also participants in the CNS system of the NSCC (the ''NSCC Process'') or through a manual clearing process that is available to all DTC Participants (the ''DTC Process'').

5. In order to keep costs low and permit each Fund to be as fully invested as possible, Shares will be purchased and redeemed in Creation Units and generally on an in-kind basis. Accordingly, except where the purchase or redemption will include cash under the limited circumstances specified below, purchasers will be required to purchase Creation Units by making an in-kind deposit of specified instruments (''Deposit Instruments''), and shareholders redeeming their Shares will receive an in-kind transfer of specified instruments (''Redemption Instruments'').[5] On any given Business Day [6] the names and quantities of the instruments that constitute the Deposit Instruments and the names and quantities of the instruments that constitute the Redemption Instruments will be identical, and these instruments may be referred to, in the case of either a purchase or redemption, as the ''Creation Basket.'' In addition, the Creation Basket will correspond pro rata to the positions in a Fund's portfolio (including cash positions),[7] except: (a) In the case of bonds, for minor differences when it is impossible to break up bonds beyond certain minimum sizes needed for transfer and settlement; (b) for minor differences when rounding is necessary to eliminate fractional shares or lots that are not tradeable round lots; [8] or (c) TBA Transactions and other positions that cannot be transferred in kind [9] will be excluded from the Creation Basket.[10] If there is a difference between the net asset value (''NAV'') attributable to a Creation Unit and the aggregate market value of the Creation Basket exchanged for the Creation Unit, the party conveying instruments with the lower value will also pay to the other an amount in cash equal to that difference (the ''Balancing Amount'').

6. Purchases and redemptions of Creation Units may be made in whole or in part on a cash basis, rather than in kind, solely under the following circumstances: (a) To the extent there is a Balancing Amount, as described above; (b) if, on a given Business Day, a Fund announces before the open of trading that all purchases, all redemptions or all purchases and redemptions on that day will be made entirely in cash; (c) if, upon receiving a purchase or redemption order from an Authorized Participant, a Fund determines to require the purchase or redemption, as applicable, to be made entirely in cash; [11] (d) if, on a given Business Day, a Fund requires all Authorized Participants purchasing or redeeming Shares on that day to deposit or receive (as applicable) cash in lieu of some or all of the Deposit Instruments or Redemption Instruments, respectively, solely because: (i) Such instruments are not eligible for transfer through either the NSCC Process or DTC Process; or (ii) in the case of Funds holding non-U.S. investments (''Global Funds''), such instruments are not eligible for trading due to local trading restrictions, local restrictions on securities transfers or other similar circumstances; or (e) if a Fund permits an Authorized Participant to deposit or receive (as applicable) cash in lieu of some or all of the Deposit Instruments or Redemption Instruments, respectively, solely because: (i) Such instruments are, in the case of the purchase of a Creation Unit, not available in sufficient quantity; (ii) such instruments are not eligible for trading by an Authorized Participant or the investor on whose behalf the Authorized Participant is acting; or (iii) a holder of Shares of a Fund holding non-U.S. investments would be subject to unfavorable income tax treatment if the holder receives redemption proceeds in kind.[12]

7. Each Business Day, before the open of trading on the Listing Exchange, each Fund will cause to be published through the NSCC the names and quantities of the instruments comprising the Creation Basket, as well as the estimated Balancing Amount (if any), for that day. The published Creation Basket will apply until a new Creation Basket is announced on the following Business Day, and there will be no intra-day changes to the Creation Basket except to correct errors in the published Creation Basket. The Listing Exchange or a major market data vendor will disseminate every 15 seconds throughout the trading day an amount representing the Fund's estimated NAV, which will be the value of the Fund's Portfolio Positions, on a per Share basis.

8. An investor purchasing or redeeming a Creation Unit will be charged a fee (''Transaction Fee'') to protect existing shareholders of the Funds from the dilutive costs associated with the purchase and redemption of Creation Units.[13] The Distributor will deliver a confirmation and Fund prospectus (''Prospectus'') to the purchaser. In addition, the Distributor

[5] The Funds must comply with the federal securities laws in accepting Deposit Instruments and satisfying redemptions with Redemption Instruments, including that the Deposit Instruments and Redemption Instruments are sold in transactions that would be exempt from registration under the Securities Act. In accepting Deposit Instruments and satisfying redemptions with Redemption Instruments that are restricted securities eligible for resale pursuant to Rule 144A under the Securities Act, the Funds will comply with the conditions of Rule 144A.

[6] Each Fund will sell and redeem Creation Units on any day the Fund is open, including as required by section 22(e) of the Act (each, a ''Business Day'').

[7] The portfolio used for this purpose will be the same portfolio used to calculate the Fund's NAV for that Business Day.

[8] A tradeable round lot for a security will be the standard unit of trading in that particular type of security in its primary market.

[9] This includes instruments that can be transferred in kind only with the consent of the original counterparty to the extent the Fund does not intend to seek such consents.

[10] Because these instruments will be excluded from the Creation Basket, their value will be reflected in the determination of the Balancing Amount (defined below).

[11] In determining whether a particular Fund will sell or redeem Creation Units entirely on a cash or in-kind basis (whether for a given day or a given order), the key consideration will be the benefit that would accrue to the Fund and its investors. For instance, in bond transactions, the Adviser may be able to obtain better execution than Share purchasers because of the Adviser's size, experience and potentially stronger relationships in the fixed income markets. Purchases of Creation Units either on an all cash basis or in-kind are expected to be neutral to the Funds from a tax perspective. In contrast, cash redemptions typically require selling portfolio holdings, which may result in adverse tax consequences for the remaining Fund shareholders that would not occur with an in-kind redemption. As a result, tax considerations may warrant in-kind redemptions.

[12] A ''custom order'' is any purchase or redemption of Shares made in whole or in part on a cash basis in reliance on clause (e)(i) or (e)(ii).

[13] Where a Fund, under the procedures described above, permits an in-kind purchaser to substitute cash for a portion of the Deposit Instruments, the purchaser may be assessed a higher Transaction Fee to offset the cost to the Fund of buying those particular Deposit Securities.

will maintain records of both the orders placed with it and the confirmations of acceptance furnished by it.

9. Beneficial owners of Shares may sell their Shares in the secondary market. Shares will be listed on a Listing Exchange and traded in the secondary market in the same manner as other equity securities. Applicants state that one or more specialists or market makers will be assigned to the Shares.[14] The price of Shares trading on the secondary market will be based on a current bid-offer market. Transactions involving the sale of Shares on the Listing Exchange will be subject to customary brokerage commissions and charges.

10. Applicants expect that purchasers of Creation Units will include arbitrageurs and that Listing Exchange specialists or market makers, acting in their unique role to provide a fair and orderly secondary market for Shares, also may purchase Creation Units for use in their own market making activities. Applicants expect that secondary market purchasers of Shares will include both institutional investors and retail investors.[15] Applicants state that because the market price of Creation Units will be disciplined by arbitrage opportunities, investors should be able to sell Shares in the secondary market at prices that do not vary materially from their NAV.

11. Neither the Company nor any Fund will be advertised or marketed as a conventional open-end investment company or mutual fund. Instead, each Fund will be marketed as an ''actively-managed exchange-traded fund.'' Any advertising material that describes the features of obtaining, buying or selling Creation Units, or buying or selling Shares on the Listing Exchange, or where there is reference to redeemability, will prominently disclose that Shares are not individually redeemable and that owners of Shares may acquire Shares from a Fund and tender those Shares for redemption to a Fund in Creation Units only.

12. The Funds' Web site, which will be publicly available prior to the public offering of Shares, will include, or will include links to, each Fund's current Prospectus and Summary Prospectus (if any), which may be downloaded. That Web site, which will be publicly available at no charge, will also contain, on a per Share basis for each Fund, the prior Business Day's NAV and the market closing price or the mid-point of the bid/ask spread at the time of calculation of such NAV (the ''Bid/Ask Price''), and a calculation of the premium or discount of the market closing price or Bid/Ask Price against such NAV. On each Business Day, before commencement of trading in Shares on the Listing Exchange, each Fund will also disclose on the Web site the identities and quantities of its Portfolio Positions held by the Fund that will form the basis for the Fund's calculation of NAV at the end of the Business Day.[16]

Applicants' Legal Analysis

1. Applicants request an order under section 6(c) of the Act for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c–1 under the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and (a)(2) of the Act.

2. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction, or any class of persons, securities or transactions, from any provision of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from section 17(a) of the Act if evidence establishes that the terms of the proposed transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the proposed transaction is consistent with the policies of the registered investment company and the general provisions of the Act.

Sections 5(a)(1) and 2(a)(32) of the Act

3. Section 5(a)(1) of the Act defines an ''open-end company'' as a management investment company that is offering for sale or has outstanding any redeemable security of which it is the issuer. Section 2(a)(32) of the Act defines a redeemable security as any security, other than short-term paper, under the terms of which the holder, upon its presentation to the issuer, is entitled to receive approximately a proportionate share of the issuer's current net assets, or the cash equivalent. Applicants request an order to permit the Company to register as an open-end management investment company and redeem Shares in Creation Units only. Applicants state that each investor is entitled to purchase or redeem Creation Units rather than trade the individual Shares in the secondary market. Applicants further state that because of the arbitrage possibilities created by the redeemability of Creation Units, it is expected that the market price of an individual Share will not vary materially from its NAV.

Section 22(d) of the Act and Rule 22c–1 Under the Act

4. Section 22(d) of the Act, among other things, prohibits a dealer from selling a redeemable security, which is currently being offered to the public by or through a principal underwriter, except at a current public offering price described in the prospectus. Rule 22c–1 under the Act generally requires that a dealer selling, redeeming, or repurchasing a redeemable security do so only at a price based on its NAV. Applicants state that secondary market trading in Shares will take place at negotiated prices, rather than at the current offering price described in the Fund's Prospectus. Thus, purchases and sales of Shares in the secondary market will not comply with section 22(d) of the Act and rule 22c–1 under the Act. Applicants request an exemption under section 6(c) from these provisions.

5. Applicants assert that the concerns sought to be addressed by section 22(d) of the Act and rule 22c–1 under the Act with respect to pricing are equally satisfied by the proposed method of pricing Shares. Applicants maintain that while there is little legislative history regarding section 22(d), its provisions, as well as those of rule 22c–1, appear to have been intended (a) to prevent dilution caused by certain riskless-trading schemes by principal underwriters and contract dealers, (b) to prevent unjust discrimination or preferential treatment among buyers, and (c) to ensure an orderly distribution of shares by eliminating price competition from brokers offering shares at less than the published sales price and repurchasing shares at more than the published redemption price.

[14] If Shares are listed on NASDAQ, no specialist would be contractually obligated to make a market in Shares. Rather, under NASDAQ's listing requirements, two or more Market Makers will be registered in Shares and required to make a continuous, two-sided market or face regulatory sanctions. Applicants do not believe that any characteristics of a NASDAQ listing would cause Shares to operate or trade differently than if they were listed on another Listing Exchange.

[15] Shares will be registered in book-entry form only. DTC or its nominee will be the record or registered owner of all outstanding Shares. DTC or DTC Participants will maintain records of beneficial ownership of Shares.

[16] Under accounting procedures followed by the Funds, trades made on the prior Business Day (''T'') will be booked and reflected in NAV on the current Business Day (''T+1''). Accordingly, the Funds will be able to disclose at the beginning of the Business Day the portfolio that will form the basis for the NAV calculation at the end of the Business Day.

6. Applicants state that (a) secondary market transactions in Shares would not cause dilution for owners of such Shares because such transactions do not involve the Company or Funds as parties, and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces, such as supply and demand. Therefore, applicants assert that secondary market transactions in Shares will not lead to discrimination or preferential treatment among purchasers. Finally, applicants contend that the proposed distribution system will be orderly because arbitrage activity will ensure that the difference between the market price of Shares and their NAV remains immaterial.

Section 22(e)

7. Section 22(e) of the Act generally prohibits a registered investment company from suspending the right of redemption or postponing the date of payment of redemption proceeds for more than seven days after the tender of a security for redemption. Applicants observe that the settlement of redemptions of Creation Units of Global Funds will be contingent not only on the settlement cycle of the U.S. securities markets but also on the delivery cycles in foreign markets in which those Funds invest. Applicants assert that, under certain circumstances, the delivery cycles for transferring Portfolio Positions to redeeming investors, coupled with local market holiday schedules, may require a delivery process of up to 14 calendar days. Applicants therefore request relief from section 22(e) in order for each Global Fund to provide payment or satisfaction of redemptions within the maximum number of calendar days required for such payment or satisfaction in the principal local market(s) where transactions in its Portfolio Positions customarily clear and settle, but in any event, within a period not to exceed fourteen calendar days.[17]

8. Applicants submit that Congress adopted section 22(e) to prevent unreasonable, undisclosed or unforeseen delays in the actual payment of redemption proceeds. Applicants state that allowing redemption payments for Creation Units of a Global Fund to be made within 14 calendar days would not be inconsistent with the spirit and intent of section 22(e). Applicants state that each Global Fund's statement of additional information (''SAI'') will disclose those local holidays (over the period of at least one year following the date of the SAI), if any, that are expected to prevent the delivery of redemption proceeds in seven calendar days and the maximum number of days, up to 14 calendar days, needed to deliver the proceeds for that Global Fund. Applicants are not seeking relief from section 22(e) with respect to Global Funds that do not effect redemptions of Creation Units in-kind.

Sections 17(a)(1) and (2) of the Act

9. Section 17(a)(1) and (2) of the Act generally prohibit an affiliated person of a registered investment company, or an affiliated person of such a person (''second tier affiliate''), from selling any security to or purchasing any security from the company. Section 2(a)(3) of the Act defines ''affiliated person'' to include any person directly or indirectly owning, controlling, or holding with power to vote 5% or more of the outstanding voting securities of the other person and any person directly or indirectly controlling, controlled by, or under common control with, the other person. Section 2(a)(9) of the Act defines ''control'' of a fund as ''the power to exercise a controlling influence over the management or policies'' of the fund and provides that a control relationship will be presumed where one person owns more than 25% of another person's voting securities. The Funds may be deemed to be controlled by an Adviser and hence affiliated persons of each other. In addition, the Funds may be deemed to be under common control with any other registered investment company (or series thereof) advised by an Adviser (an ''Affiliated Fund'').

10. Applicants request an exemption from section 17(a) under sections 6(c) and 17(b) to permit in-kind purchases and redemptions of Creation Units from the Funds by persons that are affiliated persons or second tier affiliates of the Funds solely by virtue of one or more of the following: (1) Holding 5% or more, or more than 25%, of the outstanding Shares of one or more Funds; (2) an affiliation with a person with an ownership interest described in (1); or (3) holding 5% or more, or more than 25%, of the shares of one or more Affiliated Funds.

11. Applicants assert that no useful purpose would be served by prohibiting the affiliated persons described above from making in-kind purchases or in-kind redemptions of Shares of a Fund in Creation Units. Both the deposit procedures for in-kind purchases of Creation Units and the redemption procedures for in-kind redemptions will be effected in exactly the same manner for all purchases and redemptions. The valuation of the Deposit Instruments and Redemption Instruments will be made in the same manner, and in the same manner as the Fund's Portfolio Positions, regardless of the identity of the purchaser or redeemer. Except with respect to cash determined in accordance with the procedures described in section I.G.1. of the application, Deposit Instruments and Redemption Instruments will be the same for all purchasers and redeemers. Therefore, applicants state that the in-kind purchases and redemptions will afford no opportunity for the specified affiliated persons of a Fund to effect a transaction detrimental to other holders of Shares of that Fund. Applicants do not believe that in-kind purchases and redemptions will result in abusive self-dealing or overreaching of the Fund.

Applicant's Conditions

Applicants agree that any order of the Commission granting the requested relief will be subject to the following conditions:

1. As long as the Funds operate in reliance on the requested order, the Shares of the Funds will be listed on a Listing Exchange.

2. Neither the Company nor any Fund will be advertised or marketed as an open-end investment company or a mutual fund. Any advertising material that describes the purchase or sale of Creation Units or refers to redeemability will prominently disclose that the Shares are not individually redeemable and that owners of the Shares may acquire those Shares from the Fund and tender those Shares for redemption to the Fund in Creation Units only.

3. The Web site for the Funds, which is and will be publicly accessible at no charge, will contain on a per Share basis, for each Fund, the prior Business Day's NAV and the market closing price or Bid/Ask Price, and a calculation of the premium or discount of the market closing price or Bid/Ask Price against such NAV.

4. On each Business Day, before commencement of trading in Shares on the Listing Exchange, the Fund will disclose on its Web site the identities and quantities of the Portfolio Positions held by the Fund that will form the basis for the Fund's calculation of NAV at the end of the Business Day.

5. The Adviser or any Fund Sub-Adviser, directly or indirectly, will not cause any Authorized Participant (or any investor on whose behalf an Authorized Participant may transact

[17] Applicants acknowledge that no relief obtained from the requirements of section 22(e) will affect any obligations that they may otherwise have under rule 15c6–1 under the Exchange Act, which requires that most securities transactions be settled within three business days of the trade date.

with the Fund) to acquire any Deposit Instrument for the Fund through a transaction in which the Fund could not engage directly.

6. The requested relief to permit ETF operations will expire on the effective date of any Commission rule under the Act that provides relief permitting the operation of actively managed exchange-traded funds.

For the Commission, by the Division of Investment Management, under delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–10890 Filed 5–7–13; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69502; File No. SR–NYSE–2013–30]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rule 13 to Expand the Availability of Self-Trade Prevention Modifiers

May 2, 2013.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on April 22, 2013, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 13 to expand the availability of self-trade prevention (''STP'') modifiers. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 13 to expand the availability of STP modifiers functionality to additional order types.[4] STP modifiers are designed to prevent two orders from the same market participant identifier (''MPID'') assigned to a member organization from executing against each other. Use of the STP modifiers is optional and is not automatically implemented by the Exchange. Rather, a member organization can choose to add a STP modifier on eligible orders. The STP modifier on the incoming order determines the interaction between two orders marked with STP modifiers and whether the incoming or the resting order would cancel. Both the buy and the sell order must include an STP modifier in order to prevent a trade from occurring and to effect a cancel instruction.

The Exchange proposes to make STP modifiers available to additional order types. Specifically, the Exchange proposes to make STP modifiers available for market orders and stop orders entered by off-Floor participants in a manner that is similar to limit orders. As proposed, the STP modifiers would be available for market orders and stop orders sent to the matching engine by off-Floor participants. Because of technology issues, the Exchange would continue to reject all GTC and MTS-IOC orders with an STP modifier.

In addition, the Exchange proposes to make the STP modifier available for certain Floor broker interest. In adopting STP modifiers, the Exchange noted that the technology supporting the proposed STP modifiers was not compatible with the Floor broker systems, but the Exchange was actively working to develop the technology to extend STP modifiers to be available for Floor brokers.[5] The Exchange did not believe it should delay the deployment of the STP modifiers for other market participants while it performed the technical modifications required for the use of STP modifiers for Floor brokers. Although the technology supporting STP modifiers is still not compatible with certain Floor broker systems, the Exchange is able to make the STP modifiers available to algorithms used by Floor brokers to route interest to the Exchange's matching engine. Accordingly, the Exchange proposes to make STP modifiers available for e-Quotes, pegging e-Quotes, and g-Quotes entered into the matching engine by an algorithm on behalf of a Floor broker. STP modifiers would not be available for d-Quotes at this time, regardless of the system used to enter d-Quotes.

Because of the technology changes associated with this rule proposal, the Exchange will announce the implementation date of the STP modifiers in a Trader Update to be published no later than 60 days after the publication of the notice in the **Federal Register**. The implementation date will be no later than 60 days following publication of the Trader Update announcing publication of the notice in the **Federal Register**.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6(b) [6] of the Securities Exchange Act of 1934 (the ''Act''), in general, and furthers the objectives of Section 6(b)(5) [7] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system. The Exchange believes that expanding the availability STP functionality to additional order types would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would allow firms to better manage order flow and prevent unintended executions with themselves or the

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange recently amended Rule 13 to add STP Modifiers. *See* Securities Exchange Act Release No. 69102 (Mar. 11, 2013), 78 FR 16561 (Mar. 15, 2013) (SR–NYSE–2013–17).

[5] *See id.*

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

potential for ''wash sales'' that may occur as a result of the velocity of trading in today's high-speed marketplace. Commonly, member organizations have multiple connections into the Exchange due to capacity and speed-related demands. Orders routed by member organizations via different connections may, in certain circumstances, inadvertently trade against each other. Enabling STP modifiers for market orders and stop orders would provide member organizations with the opportunity to prevent these unintended trades from occurring.

By providing STP modifier functionality to certain e-Quotes, pegging e-Quotes, and g-Quotes entered algorithmically, the proposal provides Floor brokers with the opportunity to prevent these unintended trades from occurring as well. The Exchange believes that offering STP modifiers to Floor broker interest entered via algorithms removes impediments to and perfects the mechanism of a free and open market because there is a greater potential for unintended consequences for interest entered via algorithms, because of the above-noted velocity of trading, as compared to orders entered manually. The Exchange will continue to work to develop technology to extend STP modifiers for other Floor broker systems as well. The Exchange notes that all Floor brokers have access to algorithms, and therefore this functionality will be available to all Floor brokers. The Exchange further notes that the STP modifiers would not alleviate, or otherwise exempt, broker-dealers from their best execution obligations.

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 proposal will provide member organizations and Floor brokers with the opportunity to prevent unintended self-trades from occurring. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues who offer similar functionality. Many competing venues offer similar functionality to market participants. To this end, the Exchange is proposing a market enhancement to provide greater protections from inadvertent executions, and encourage market participants to trade on the Exchange. The Exchange believes the proposed rule change is pro-competitive because it would enable the Exchange to provide Floor brokers with functionality that is similar to that of other exchanges and available for interest entered electronically from off of the Floor.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [8] and Rule 19b–4(f)(6) [9] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [10] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2013–30 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2013–30. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2013–30 and should be submitted on or before May 29, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–10901 Filed 5–7–13; 8:45 am]

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[8] 15 U.S.C. 78s(b)(3)(A).

[9] 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 filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[10] 15 U.S.C. 78s(b)(2)(B).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69499; File No. SR–NASDAQ–2013–070]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing of Proposed Rule Change for the Permanent Approval of a Pilot Program To Permit NOM To Accept Inbound Options Orders From NASDAQ OMX BX, Inc.

May 2, 2013.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on April 24, 2013, The NASDAQ Stock Market LLC (the ''Exchange'' or ''Nasdaq'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is seeking permanent approval of its pilot program to permit the NASDAQ Options Market (''NOM'') to accept inbound options orders routed by Nasdaq Options Services LLC (''NOS'') from NASDAQ OMX BX, Inc. (''BX'').

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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

In conjunction with BX providing outbound routing services to all options markets using its affiliated routing broker, NOS,[4] NASDAQ proposed that NOS be permitted to route orders from BX to NOM on a pilot basis, subject to certain limitations and conditions, as described below.[5] The current pilot program expires June 28, 2013. NOS is a broker-dealer and member of NASDAQ, NASDAQ OMX PHLX LLC (''Phlx'') and BX. NOS provides all routing functions for BX Options, Phlx and NOM. BX, NASDAQ, NOM, Phlx and NOS are affiliates.[6] Accordingly, the affiliate relationship between NASDAQ and NOS, its member, raises the issue of an exchange's affiliation with a member of such exchange. Specifically, in connection with prior filings, the Commission has expressed concern that the affiliation of an exchange with one of its members raises the potential for unfair competitive advantage and potential conflicts of interest between an exchange's self-regulatory obligations and its commercial interests.[7]

Recognizing that the Commission has previously expressed concern regarding the potential for conflicts of interest in instances where a member firm is affiliated with an exchange of which it is a member, the Exchange previously proposed, and the Commission approved, limitations and conditions on NOS's affiliation with the Exchange.[8] Also recognizing that the Commission has expressed concern regarding the potential for conflicts of interest in instances where a member firm is affiliated with an exchange to which it is routing orders, the Exchange previously proposed, and the Commission approved,[9] NOS's affiliation with the Exchange to permit the Exchange to accept inbound orders that NOS routes in its capacity as a facility of BX, subject to the certain limitations and conditions. The Exchange now proposes to permit NOM to accept inbound options orders that NOS routes in its capacity as a facility of BX on a permanent basis, subject to the limitations and conditions of this pilot:

- First, the Exchange and FINRA maintain a Regulatory Contract, as well as an agreement pursuant to Rule 17d–2 under the Act (''17d–2 Agreement'').[10] Pursuant to the Regulatory Contract and the 17d–2 Agreement, FINRA is allocated regulatory responsibilities to review NOS's compliance with certain Exchange rules.[11] Pursuant to the Regulatory Contract, however, NASDAQ retains ultimate responsibility for enforcing its rules with respect to NOS.
- Second, FINRA monitors NOS for compliance with the Exchange's trading rules, and collects and maintains certain related information.[12]
- Third, FINRA provides a report to the Exchange's chief regulatory officer (''CRO''), on a quarterly basis, that: (i) Quantifies all alerts (of which FINRA is aware) that identify NOS as a participant that has potentially violated Commission or Exchange rules, and (ii) lists all investigations that identify NOS as a participant that has potentially violated Commission or Exchange rules.
- Fourth, the Exchange has in place NASDAQ Rule 2140(c) [sic], which requires The NASDAQ OMX Group, Inc., as the holding company owning both the Exchange and NOS, to establish and maintain procedures and internal controls reasonably designed to ensure that NOS does not develop or implement changes to its system, based on non-public information obtained regarding planned changes to the Exchange's systems as a result of its affiliation with the Exchange, until such information is available generally to

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] Securities Exchange Act Release No. 67256 (June 26, 2012), 77 FR 39277 (July 2, 2012) (SR–BX–2012–030).

[5] *See* Securities Exchange Act Release No. 67295 (June 28, 2012), 77 FR 39758 (July 5, 2012) (SR–NASDAQ–2012–061).

[6] *See* Securities Exchange Act Release Nos. 58324 (August 7, 2008), 73 FR 46936 (August 12, 2008) (SR–BSE–2008–02; SR–BSE–2008–23; SR–BSE–2008–25; SR–BSECC–2008–01) (order approving NASDAQ OMX's acquisition of BX); and 58179 (July 17, 2008), 73 FR 42874 (July 23, 2008) (SR–Phlx–2008–31) (order approving NASDAQ OMX's acquisition of Phlx).

[7] *See* Securities Exchange Act Release Nos. 59153 (December 23, 2008), 73 FR 80485 (December 31, 2008) (SR–NASDAQ–2008–098); and 62736 (August 17, 2010), 75 FR 51861 (August 23, 2010) (SR–NASDAQ–2010–100). *See also* Securities Exchange Act Release No. 58135 (July 10, 2008), 73 FR 40898 (July 16, 2008) (SR–NASDAQ–2008–061) (permitting NOS to be affiliated with Phlx).

[8] *See* Securities Exchange Act Release No. 67295 (June 28, 2012), 77 FR 39758 (July 5, 2012) (SR–NASDAQ–2012–061). *See also* Securities Exchange Act Release No. 57478 (March 12, 2008), 73 FR 14521 (March 18, 2008) (Order Approving File Nos. SR–NASDAQ–2007–004 and SR–NASDAQ–2007–080).

[9] *See* Securities Exchange Act Release No. 67295 (June 28, 2012), 77 FR 39758 (July 5, 2012) (SR–NASDAQ–2012–061).

[10] 17 CFR 240.17d–2.

[11] NOS is also subject to independent oversight by FINRA, its designated examining authority, for compliance with financial responsibility requirements.

[12] Pursuant to the Regulatory Contract, both FINRA and the Exchange collect and maintain all alerts, complaints, investigations and enforcement actions in which NOS (in its capacity as a facility of BX routing orders to NOM) is identified as a participant that has potentially violated applicable Commission or Exchange rules. The Exchange and FINRA retain these records in an easily accessible manner in order to facilitate any potential review conducted by the Commission's Office of Compliance Inspections and Examinations.

similarly situated Exchange members, in connection with the provision of inbound order routing to the Exchange.

The Exchange has met all the above-listed conditions. By meeting the above conditions, the Exchange has set up mechanisms that protect the independence of the Exchange's regulatory responsibility with respect to NOS, as well as demonstrate that NOS cannot use any information advantage it may have because of its affiliation with the Exchange. Because the Exchange has met all the above-listed conditions, it now seeks permanent approval of this inbound routing relationship. The Exchange will continue to comply with the conditions 1–4 stated above.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[13] in general, and with Sections 6(b)(5) of the Act,[14] in particular, in that the proposal is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, because the proposed rule change will allow the Exchange to continue to receive inbound orders from NOS, acting in its capacity as a facility of BX, in a manner consistent with prior approvals and established protections. The Exchange believes that these conditions establish mechanisms that protect the independence of the Exchange's regulatory responsibility with respect to NOS, as well as ensure that NOS cannot use any information it may have because of its affiliation with the Exchange to its advantage.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. Permanent approval of the current pilot program does not raise any issues of intra-market competition because it involves inbound routing from an affiliated exchange. Nor does it result in a burden on competition among exchanges, because there are many competing options exchanges that provide routing services, including through an affiliate.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2013–070 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2013–070. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NASDAQ–2013–070 and should be submitted on or before May 29, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Kevin M. O'Neill,

Deputy Secretary.

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[13] 15 U.S.C. 78f.

[14] 15 U.S.C. 78f(b)(5).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69501; File No. SR–NYSEMKT–2013–36]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rule 13—Equities To Expand the Availability of Self-Trade Prevention Modifiers

May 2, 2013.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on April 22, 2013, NYSE MKT LLC (''NYSE MKT'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 13—Equities to expand the availability of self-trade prevention (''STP'') modifiers. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 13—Equities to expand the availability of STP modifiers functionality to additional order types.[4] STP modifiers are designed to prevent two orders from the same market participant identifier (''MPID'') assigned to a member organization from executing against each other. Use of the STP modifiers is optional and is not automatically implemented by the Exchange. Rather, a member organization can choose to add a STP modifier on eligible orders. The STP modifier on the incoming order determines the interaction between two orders marked with STP modifiers and whether the incoming or the resting order would cancel. Both the buy and the sell order must include an STP modifier in order to prevent a trade from occurring and to effect a cancel instruction.

The Exchange proposes to make STP modifiers available to additional order types. Specifically, the Exchange proposes to make STP modifiers available for market orders and stop orders entered by off-Floor participants in a manner that is similar to limit orders. As proposed, the STP modifiers would be available for market orders and stop orders sent to the matching engine by off-Floor participants. Because of technology issues, the Exchange would continue to reject all GTC and MTS–IOC orders with an STP modifier.

In addition, the Exchange proposes to make the STP modifier available for certain Floor broker interest. In adopting STP modifiers, the Exchange noted that the technology supporting the proposed STP modifiers was not compatible with the Floor broker systems, but the Exchange was actively working to develop the technology to extend STP modifiers to be available for Floor brokers.[5] The Exchange did not believe it should delay the deployment of the STP modifiers for other market participants while it performed the technical modifications required for the use of STP modifiers for Floor brokers. Although the technology supporting STP modifiers is still not compatible with certain Floor broker systems, the Exchange is able to make the STP modifiers available to algorithms used by Floor brokers to route interest to the Exchange's matching engine. Accordingly, the Exchange proposes to make STP modifiers available for e-Quotes, pegging e-Quotes, and g-Quotes entered into the matching engine by an algorithm on behalf of a Floor broker. STP modifiers would not be available for d-Quotes at this time, regardless of the system used to enter d-Quotes.

Because of the technology changes associated with this rule proposal, the Exchange will announce the implementation date of the STP modifiers in a Trader Update to be published no later than 60 days after the publication of the notice in the **Federal Register**. The implementation date will be no later than 60 days following publication of the Trader Update announcing publication of the notice in the **Federal Register**.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6(b)[6] of the Securities Exchange Act of 1934 (the ''Act''), in general, and furthers the objectives of Section 6(b)(5)[7] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system. The Exchange believes that expanding the availability STP functionality to additional order types would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would allow firms to better manage order flow and prevent unintended executions with themselves or the potential for ''wash sales'' that may occur as a result of the velocity of trading in today's high-speed marketplace. Commonly, member organizations have multiple connections into the Exchange due to capacity and speed-related demands. Orders routed by member organizations via different connections may, in certain circumstances, inadvertently trade against each other. Enabling STP modifiers for market orders and stop orders would provide member organizations with the opportunity to prevent these unintended trades from occurring.

By providing STP modifier functionality to certain e-Quotes, pegging e-Quotes, and g-Quotes entered algorithmically, the proposal provides Floor brokers with the opportunity to prevent these unintended trades from occurring as well. The Exchange believes that offering STP modifiers to Floor broker interest entered via algorithms removes impediments to and perfects the mechanism of a free and open market because there is a greater potential for unintended consequences for interest entered via algorithms, because of the above-noted velocity of trading, as compared to orders entered manually. The Exchange will continue to work to develop technology to extend STP modifiers for other Floor broker systems as well. The Exchange notes that all Floor brokers have access to algorithms, and therefore this functionality will be available to all Floor brokers. The Exchange further notes that the STP modifiers would not alleviate, or otherwise exempt, broker-dealers from their best execution obligations.

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 proposal will would provide member organizations

[4] The Exchange recently amended Rule 13—Equities to add STP Modifiers. *See* Securities Exchange Act Release No. 69098 (Mar. 11, 2013), 78 FR 16544 (Mar. 15, 2013) (SR–NYSEMKT–2013–21).

[5] *See id.*

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

and Floor brokers with the opportunity to prevent unintended self-trades from occurring. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues who offer similar functionality. Many competing venues offer similar functionality to market participants. To this end, the Exchange is proposing a market enhancement to provide greater protections from inadvertent executions, and encourage market participants to trade on the Exchange. The Exchange believes the proposed rule change is pro-competitive because it would enable the Exchange to provide Floor brokers with functionality that is similar to that of other exchanges and available for interest entered electronically from off of the Floor.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [8] and Rule 19b–4(f)(6) [9] thereunder.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEMKT–2013–36 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2013–36. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2013–36 and should be submitted on or before May 29, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Kevin M. O'Neill,

Deputy Secretary.

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[8] 15 U.S.C. 78s(b)(3)(A).

[9] 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 filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69494; File No. SR–DTC–2013–03]

Self-Regulatory Organizations; the Depository Trust Company; Notice of Filing of Proposed Rule Change in Connection With the Implementation of the Foreign Account Tax Compliance Act (FATCA)

May 2, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 22, 2013 The Depository Trust Company (''DTC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been substantially prepared by DTC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change modifies DTC's Rules & Procedures (''Rules''), as described below, in connection with the implementation of sections 1471 through 1474 of the Internal Revenue Code of 1986, as amended, which sections were enacted as part of the Foreign Account Tax Compliance Act, and the Treasury Regulations or other official interpretations thereunder (collectively ''FATCA'').

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, DTC 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. DTC has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.[3]

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Background

FATCA was enacted on March 18, 2010, as part of the Hiring Incentives to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission has modified the text of the summaries prepared by the clearing agency.

Restore Employment Act, and became effective, subject to transition rules, on January 1, 2013. The U.S. Treasury Department finalized and issued various implementing regulations (''FATCA Regulations'') on January 17, 2013. FATCA's intent is to curb tax evasion by U.S. citizens and residents through their use of offshore bank accounts. FATCA generally requires foreign financial institutions (''FFIs'')[4] to become ''participating FFIs'' by entering into agreements with the Internal Revenue Service (''IRS''). Under these agreements, FFIs are required to report to the IRS information on U.S. persons and entities that have (directly or indirectly) accounts with these FFIs. If an FFI does not enter into such an agreement with the IRS, FATCA will impose a 30% withholding tax on U.S.-source interest, dividends and other periodic amounts paid to such ''nonparticipating FFI'' (''Income Withholding''), as well as on the payment of gross proceeds arising from the sale, maturity or redemption of securities or any instrument yielding U.S.-source interest and dividends (''Gross Proceeds Withholding,'' and, together with Income Withholding, ''FATCA Withholding''). The 30% FATCA Withholding taxes will apply to payments made to a nonparticipating FFI acting in any capacity, including payments made to a nonparticipating FFI that is not the beneficial owner of the amount paid and acting only as a custodian or other intermediary with respect to such payment. To the extent that U.S.-source interest, dividend, and other periodic amount or gross proceeds payments are due to a nonparticipating FFI in any capacity, a U.S. payor, such as DTC, transmitting such payments to the nonparticipating FFI will be liable to the IRS for any amounts of FATCA Withholding that the U.S. payor should, but does not, withhold and remit to the IRS with respect to those payments.

As an alternative to FFIs entering into individual agreements with the IRS, the U.S. Treasury Department provided another means of complying with FATCA for FFIs which are resident in jurisdictions that enter into intergovernmental agreements (''IGA'') with the United States.[5] Generally, such a foreign jurisdiction (''FATCA Partner'') would pass laws to eliminate the conflicts of law issues that would otherwise make it difficult for FFIs in its jurisdiction to collect the information required under FATCA and transfer this information, directly or indirectly, to the United States. An FFI resident in a FATCA Partner jurisdiction would either transmit FATCA reporting to its local competent tax authority, which in turn would transmit the information to the IRS, or the FFI would be authorized/required by FATCA Partner law to enter into an FFI agreement and transmit FATCA reporting directly to the IRS. Under both IGA models, payments to such FFIs would not be subject to FATCA Withholding taxes so long as the FFI complies with the FATCA Partner's laws mandated in the IGA.

Under the FATCA Regulations, (A) beginning January 1, 2014, DTC will be required to do Income Withholding on any payments made to any nonparticipating FFI approved for membership by DTC as of such date or thereafter, (B) beginning July 1, 2014, DTC will be required to do Income Withholding on any payments made to any nonparticipating FFI approved for membership by DTC prior to January 1, 2014 and (C) beginning January 1, 2017, DTC will be required to do Gross Proceeds Withholding on all nonparticipating FFIs, regardless when any such FFI's membership was approved.

DTC already has established tax services that are currently available to its Participants in which DTC, in accordance with sections 1441 through 1446 of the Code, withholds on certain payments of income made to certain of its Participants. Thus, DTC can and intends to support certain FATCA Income Withholding as part of such established tax services. However, for the reasons described below, DTC is not in a position to accept any liability that would result from Gross Proceeds Withholding and, by making the proposed rule changes set forth herein, is implementing preventive measures to protect itself against the obligation for any such Gross Proceeds Withholding and any resulting liability.

Preparing for Implementation of FATCA

In preparation for FATCA's implementation, FFIs are being asked to identify their expected FATCA status as a condition of continuing to do business. Customary legal agreements in the financial services industry already contain provisions allocating the risk of any FATCA Withholding tax that will need to be collected, and requiring that, upon FATCA's effectiveness, foreign counterparties must certify (and periodically recertify) their FATCA status using the relevant tax forms that the IRS has announced it will provide.[3] Advance disclosure by an FFI client or counterparty would permit a withholding agent to readily determine whether it must, under FATCA, withhold on payments it makes to the FFI. If an FFI fails to provide appropriate compliance documentation to a withholding agent, such FFI would be presumed to be a nonparticipating FFI and the withholding agent will be obligated to withhold on certain payments.

As it applies to DTC specifically, FATCA will require DTC to deduct FATCA Withholding on payments to certain of its Participants arising from certain transactions processed by DTC on behalf of such Participants.[6] Because FATCA treats any entity holding financial assets for the account of others as a ''financial institution,'' and almost all Participants hold financial assets for the account of others, new and existing Participants which are treated as non-U.S. entities for federal income tax purposes, including those members and limited members that are U.S. branches of non-U.S. entities (collectively, ''FFI Participants'')[7] will likely be FFIs under FATCA. As such, DTC will be liable to the IRS for the amounts associated with any failures to withhold correctly under FATCA on payments made to its FFI Participants.

In light of this, DTC has evaluated its existing systems and services to determine whether and how it may comply with its FATCA obligations. As a result of this evaluation, DTC has determined that its existing systems are incapable of processing and accounting for Gross Proceeds Withholding with regard to the securities transactions processed by it, as no similar withholding obligation of this magnitude has ever been imposed on it to date and DTC has therefore not built systems to support such an obligation.

Additionally, DTC nets credits and debits per Participant for end of day net funds settlement. There is further netting with DTC's affiliated central counterparty, National Securities Clearing Corporation (''NSCC'') and further netting on a settling bank basis; the effect of this netting is to significantly reduce the number and magnitude of payments made via the NSS System of the Federal Reserve. Gross Proceeds Withholding would

[4] Non-U.S. financial institutions are referred to as ''foreign financial institutions'' or ''FFIs'' in the FATCA Regulations.

[5] As of the date of this proposed rule change filing, the United Kingdom, Mexico, Ireland, Switzerland, Spain, Norway, Denmark, Italy and Germany have signed or initialed an IGA with the United States. The U.S. Treasury Department has announced that it is engaged in negotiations with more than 50 countries and jurisdictions regarding entering into an IGA.

[6] FFI participants resident in IGA countries, that are compliant with the terms of applicable IGAs, should not be subject to FATCA Withholding.

[7] Currently, only a small percentage of the Corporation's Participants are treated as non-U.S. entities for federal income tax purposes.

foreclose such netting, greatly reducing liquidity available to the system and Participants, increasing systemic risk. Furthermore, given DTC's netting, undertaking Gross Proceeds Withholding could require DTC in certain circumstances to apply its Participants Fund in order to fund FATCA Withholding taxes with regard to nonparticipating FFI Participants in non-FATCA Partner jurisdictions whenever the net credit owed to such FFI Participant is less than the 30% FATCA tax. In the view of DTC, this would not be the best application of such funds which are required to support liquidity and satisfy losses attributable to the settlement activities of DTC, *inter alia.* For example, if a nonparticipating FFI is owed a $100M gross payment from the sale or maturity of U.S. securities, but such nonparticipating FFI is in a net debit settlement position at the end of that day because of DTC's end of day net crediting and debiting, and the other netting described above, there would be no payment to this FFI Participant from which DTC could withhold. In this example, DTC would likely need to fund the $30M FATCA Withholding tax until such time as the FFI Participant can reimburse DTC.[6] In that case, DTC would need to consider an increase in the amount of cash required to be deposited into the Participants Fund, either by FFI Participants or all Participants, which would reduce liquidity resources of Participants and could have significant systemic effects. The amount of the FATCA Gross Proceeds Withholding taxes would be removed from market liquidity, which could lead to increased risk of Participant failure and increased financial instability.

For the reasons explained above and the following additional reasons, DTC is proposing amendments to its Rules (detailed below) to implement preventive measures that would generally require all of DTC's FFI Participants not to cause a Gross Proceeds Withholding obligation on DTC:

- Undertaking Gross Proceeds Withholding by DTC (even if possible) would make it economically discouraging for affected FFI Participants to engage in transactions involving U.S. securities. It would likely also quickly cause a significant negative impact on liquidity because such withholding taxes would be imposed on the very large gross amounts due to such FFI Participants. Furthermore, Participants would be burdened with extra costs and the negative impact on liquidity caused by the likely need to substantially increase the amount of cash required to be deposited into the Participants Fund.
- The cost of implementing a Gross Proceeds Withholding system for a small number of nonparticipating FFI Participants would be substantial and disproportionate to the related benefit. Under the Model I IGA form and its executed versions with various FATCA Partners, DTC would not be required to withhold with regard to FFI residents in such FATCA Partner jurisdictions. Accordingly, DTC's withholding obligations under FATCA would effectively be limited to nonparticipating FFI Participants in non-FATCA Partner jurisdictions. Since the cost of developing and maintaining a complex Gross Proceeds Withholding system would be passed on to DTC's Participants at large, it may burden Participants that otherwise comply with, or are not subject to, FATCA Withholding.
- As briefly noted above, if the proposed rule changes were not to take effect, in order to avoid counterparty credit risk, DTC would likely require each of the nonparticipating FFI Participants in non-FATCA Partner jurisdictions to make initial or additional cash deposits to the Participants Fund as liquidity for the approximate potential FATCA tax liability of such nonparticipating FFI Participant or otherwise adjust required deposits to the Participants Fund. The amount of such deposits, which could amount to billions of dollars, would be removed from market liquidity.
- From the nonparticipating FFI Participant's perspective, having 30% of its payments withheld and sent to the IRS would have a severe negative impact on such nonparticipating FFI Participants' financial stability. In most cases, the gross receipts are for client accounts, and the nonparticipating FFI Participant would need to make such accounts whole. Without receipt of full payment for its dispositions, the nonparticipating FFI Participant would not have sufficient assets to fund its client accounts.
- The proposed rule changes set forth herein will not create an undue burden for Participants because requiring FFIs to certify (and to periodically recertify) their FATCA status, and imposing the costs of non-compliance on them, are becoming standard market practice in the United States, separate and apart from being a Participant of DTC.

Proposed Rule Changes

In line with its risk management focus, DTC has determined that compliance with FATCA, such that DTC shall not be responsible for Gross Proceeds Withholding, should be a general membership requirement (A) for all applicants that are treated as non-U.S. entities for U.S. federal income tax purposes, and (B) for all existing FFI Participants.[8] In connection therewith, DTC proposes to amend its Rules as follows:

- Amending Rule 1: adding ''FATCA,'' ''FATCA Certification,'' ''FATCA Compliance Date,''[9] ''FATCA Compliant,'' and ''FFI Participant'' to Section 2 as terms cross-referenced from Rule 2, Section 9;
- Amending Section 1 of Rule 2: adding the requirements that, (i) with regard to any applicant that shall be an FFI Participant, such applicant must be FATCA Compliant, and (ii) as a qualification for activation of its membership that each applicant approved by DTC complete and deliver to DTC a FATCA Certification; and
- Adding new Section 9 of Rule 2: (i) Requiring all FFI Participants (both new and existing) to agree not to conduct any transaction or activity through DTC if such Participant is not FATCA Compliant, (ii) requiring all FFI Participants to certify and, as required under the timelines set forth under FATCA, periodically recertify, to DTC, in accordance with the timelines set out under FATCA, that they are FATCA Compliant, (iii) specifying that failure to be FATCA Compliant creates a duty upon an FFI Member (both new and existing) to inform DTC, (iv) providing that Participants that violate the provisions of Section 9 are subject to disciplinary sanction or other applicable actions by DTC in accordance with the Rules, including, but not limited to, a fine, as well as restrictions of services to the Participant and/or ceasing to act for the Participant in accordance with Rule 10, and (v) requiring all FFI Participants to indemnify DTC for any losses sustained by DTC resulting from such FFI Participants' failure to be FATCA Compliant. In addition, Rule 2, Section 9 will include the definitions for ''FATCA,'' ''FATCA Certification,'' ''FATCA Compliance Date,'' ''FATCA Compliant,'' and ''FFI Participant''.

[8] DTC may grant a waiver under certain circumstances, provided, however, that DTC will not grant a waiver if it causes DTC to be obligated to withhold under FATCA on gross proceeds from the sale or other disposition of any property.

[9] Although FATCA Withholding with regard to FFI Participants approved for membership by the Corporation prior to January 1, 2014 is first required under FATCA beginning July 1, 2014, the proposed amendments to the Rules would require such existing FFI Participants to be FATCA compliant approximately 60 days prior to July 1, 2014 in order for the Corporation to comply with its disciplinary and notice processes as set forth in its Rules.

• In addition, DTC will modify its *Policy Statement on the Admission of Non-U.S. Entities as Direct Depository Participants* to reference the Rules requirements of foreign entities which are treated as non-U.S. entities for tax purposes.

• Sections 17A(b)(3)(F) [10] and 17A(b)(3)(D) [11] of the Exchange Act require that registered clearing agencies be designed to promote the prompt and accurate clearance and settlement of securities transactions, and the safeguarding of funds related thereto, and that the rules of such clearing agencies provide for the equitable allocation of reasonable dues, fees, and other charges among their participants. DTC believes the proposed rule changes are designed to promote the prompt and accurate clearance and settlement of securities transactions by eliminating any uncertainty in funds settlement that would arise if DTC were subject to Gross Proceeds Withholding obligations under FATCA. The proposed rule changes are also designed to maintain fairness in the allocation of costs among Participants of DTC because these proposed rule changes allow DTC to comply with FATCA Regulations without developing and maintaining a complex Gross Proceeds Withholding system, the cost of which, as discussed above, would be passed on to DTC's Participants at large for the benefit of a small number of nonparticipating FFI Members.

(B) Clearing Agency's Statement on Burden on Competition

DTC does not believe that the proposed rule change will have any impact, or impose any burden, on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

DTC has not solicited, and does not intend to solicit, comments regarding the proposed rule changes. DTC has not received any unsolicited written comments from interested parties. To the extent DTC receives written comments on the proposed rule changes, DTC will forward such comments to the Commission.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Exchange 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–DTC–2013–03 on the subject line.

Paper Comments

• Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–DTC–2013–03. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of DTC and on DTC's Web site: *http://www.dtcc.com/legal/rule_filings/dtc/2013.php.* 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–DTC–2013–03 and should be submitted on or before May 29, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–10871 Filed 5–7–13; 8:45 am]

BILLING CODE 8011–01–P

[10] 12 U.S.C. 78q-1(b)(3)(F).

[11] 12 U.S.C. 78q-1(b)(3)(D).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69498; File No. SR–Phlx–2013–42]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing of Proposed Rule Change for the Permanent Approval of the Exchange's Pilot Program To Permit the Exchange To Accept Inbound Options Orders Routed by Nasdaq Options Services LLC From NASDAQ OMX BX, Inc.

May 2, 2013.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on April 23, 2013, NASDAQ OMX PHLX LLC (the ''Exchange'' or ''Phlx'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes a rule change for the permanent approval of the Exchange's pilot program to permit the Exchange to accept inbound options orders routed by Nasdaq Options Services LLC (''NOS'') from NASDAQ OMX BX, Inc. (''BX'').

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

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

In conjunction with BX providing outbound routing services to all options markets using its affiliated routing broker, NOS,[4] Phlx proposed that NOS be permitted to route orders from BX to Phlx on a pilot basis, subject to certain limitations and conditions, as described below.[5] The current pilot program expires June 28, 2013.

NOS is a broker-dealer and member of The NASDAQ Stock Market LLC (''NASDAQ''), PHLX and BX. NOS provides all routing functions for BX Options, Phlx, NASDAQ and NASDAQ Options Market (''NOM''). BX, NASDAQ, NOM, Phlx and NOS are affiliates.[6] Accordingly, the affiliate relationship between Phlx and NOS, its member, raises the issue of an exchange's affiliation with a member of such exchange. Specifically, in connection with prior filings, the Commission has expressed concern that the affiliation of an exchange with one of its members raises the potential for unfair competitive advantage and potential conflicts of interest between an exchange's self-regulatory obligations and its commercial interests.[7]

Recognizing that the Commission has previously expressed concern regarding the potential for conflicts of interest in instances where a member firm is affiliated with an exchange of which it is a member, the Exchange previously proposed, and the Commission approved, limitations and conditions on NOS's affiliation with the Exchange.[8] Also recognizing that the Commission has expressed concern regarding the potential for conflicts of interest in instances where a member firm is affiliated with an exchange to which it is routing orders, the Exchange previously proposed, and the Commission approved,[9] NOS's affiliation with the Exchange to permit the Exchange to accept inbound orders that NOS routes in its capacity as a facility of BX, subject to the certain limitations and conditions. The Exchange now proposes to permit Phlx to accept inbound options orders that NOS routes in its capacity as a facility of BX on a permanent basis, subject to the limitations and conditions of this pilot:

- First, the Exchange and FINRA maintain a Regulatory Contract, as well as an agreement pursuant to Rule 17d–2 under the Act (''17d–2 Agreement'').[10] Pursuant to the Regulatory Contract and the 17d–2 Agreement, FINRA is allocated regulatory responsibilities to review NOS's compliance with certain Exchange rules.[11] Pursuant to the Regulatory Contract, however, Phlx retains ultimate responsibility for enforcing its rules with respect to NOS.
- Second, FINRA monitors NOS for compliance with the Exchange's trading rules, and collects and maintains certain related information.[12]
- Third, FINRA provides a report to the Exchange's chief regulatory officer (''CRO''), on a quarterly basis, that: (i) Quantifies all alerts (of which FINRA is aware) that identify NOS as a participant that has potentially violated Commission or Exchange rules, and (ii) lists all investigations that identify NOS as a participant that has potentially violated Commission or Exchange rules.
- Fourth, the Exchange has in place Phlx Rule 985(c), which requires The NASDAQ OMX Group, Inc., as the holding company owning both the Exchange and NOS, to establish and maintain procedures and internal controls reasonably designed to ensure that NOS does not develop or implement changes to its system, based on non-public information obtained regarding planned changes to the Exchange's systems as a result of its affiliation with the Exchange, until such information is available generally to similarly situated Exchange members, in connection with the provision of inbound order routing to the Exchange.

The Exchange has met all the above-listed conditions. By meeting the above conditions, the Exchange has set up mechanisms that protect the independence of the Exchange's regulatory responsibility with respect to NOS, as well as demonstrate that NOS cannot use any information advantage it may have because of its affiliation with the Exchange. Because the Exchange has met all the above-listed conditions, it now seeks permanent approval of this inbound routing relationship. The Exchange will continue to comply with the conditions 1–4 stated above.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[13] in general, and with Sections 6(b)(5) of the Act,[14] in particular, in that the proposal is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, because the proposed rule change will allow the Exchange to continue to receive inbound orders from NOS, acting in its capacity as a facility of BX, in a manner consistent with prior approvals and established protections. The Exchange believes that these conditions establish mechanisms that protect the independence of the Exchange's regulatory responsibility with respect to NOS, as well as ensure that NOS cannot use any information it

[4] Securities Exchange Act Release No. 67256 (June 26, 2012), 77 FR 39277 (July 2, 2012) (SR–BX–2012–030).

[5] *See* Securities Exchange Act Release No. 67294 (June 28, 2012), 77 FR 39771 (July 5, 2012) (SR–Phlx–2012–68).

[6] *See* Securities Exchange Act Release Nos. 58324 (August 7, 2008), 73 FR 46936 (August 12, 2008) (SR–BSE–2008–02; SR–BSE–2008–23; SR–BSE–2008–25; SR–BSECC–2008–01) (order approving NASDAQ OMX's acquisition of BX); and 58179 (July 17, 2008), 73 FR 42874 (July 23, 2008) (SR–Phlx–2008–31) (order approving NASDAQ OMX's acquisition of Phlx).

[7] *See* Securities Exchange Act Release Nos. 59153 (December 23, 2008), 73 FR 80485 (December 31, 2008) (SR–NASDAQ–2008–098); and 62736 (August 17, 2010), 75 FR 51861 (August 23, 2010) (SR–NASDAQ–2010–100). *See also* Securities Exchange Act Release No. 58135 (July 10, 2008), 73 FR 40898 (July 16, 2008) (SR–NASDAQ–2008–061) (permitting NOS to be affiliated with Phlx).

[8] *See* Securities Exchange Act Release No. 59995 (May 28, 2009), 74 FR 26750 (June 3, 2009) (SR–Phlx–2009–32).

[9] *See* Securities Exchange Act Release No. 67294 (June 28, 2012), 77 FR 39771 (July 5, 2012) (SR–Phlx–2012–68).

[10] 17 CFR 240.17d–2.

[11] NOS is also subject to independent oversight by FINRA, its designated examining authority, for compliance with financial responsibility requirements.

[12] Pursuant to the Regulatory Contract, both FINRA and the Exchange collect and maintain all alerts, complaints, investigations and enforcement actions in which NOS (in its capacity as a facility of BX routing orders to Phlx) is identified as a participant that has potentially violated applicable Commission or Exchange rules. The Exchange and FINRA retain these records in an easily accessible manner in order to facilitate any potential review conducted by the Commission's Office of Compliance Inspections and Examinations.

[13] 15 U.S.C. 78f.

[14] 15 U.S.C. 78f(b)(5).

may have because of its affiliation with the Exchange to its advantage.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. Permanent approval of the current pilot program does not raise any issues of intra-market competition because it involves inbound routing from an affiliated exchange. Nor does it result in a burden on competition among exchanges, because there are many competing options exchanges that provide routing services, including through an affiliate.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–Phlx–2013–42 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2013–42. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2013–42 and should be submitted on or before May 29, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–10873 Filed 5–7–13; 8:45 am]

BILLING CODE 8011–01–P

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Release No. 34–69504; File No. SR–CBOE–2013–027]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Order Granting Approval of Proposed Rule Change, as Modified by Amendment No. 1, Relating to Trading Ahead of Customer Orders and Best Execution and Interpositioning Requirements

May 2, 2013.

I. Introduction

On March 5, 2013, Chicago Board Options Exchange, Incorporated (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt CBOE Rules 53.2 (Prohibition Against Trading Ahead of Customer Orders) and 53.8 (Best Execution and Interpositioning). The proposed rule change was published for comment in the **Federal Register** on March 21, 2013.[3] On April 12, 2013, CBOE filed Amendment No. 1 to the proposed rule change.[4] The Commission did not receive any comments on the proposed rule change. This order approves the proposed rule change, as modified by Amendment No. 1.

II. Description of Proposed Rule Change

The Exchange proposes to amend Rule 53.2 of the CBSX Rules, which governs the treatment of customer orders and prohibits a CBSX Trading Permit Holder from proprietarily trading ahead of a customer order, and to adopt Rule 53.8 in the CBSX Rules to govern Trading Permit Holders' best execution and interpositioning requirements. The Exchange represented that the proposed rule change is consistent with Financial Industry Regulatory Authority (''FINRA'') Rules 5320 (Prohibition Against Trading Ahead of Customer Orders)[5] and 5310 (Best Execution and Interpositioning),[6] respectively, in the Consolidated FINRA Rulebook.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 69146 (March 15, 2013); 78 FR 17454 (''Notice'').

[4] *See* Amendment No. 1 dated April 12, 2013. Amendment No. 1 corrected minor errors in the rule text of proposed Rules 53.2 and 53.8. Because Amendment No. 1 is technical in nature, it is not subject to notice and comment.

[5] *See* Securities Exchange Act Release No. 63895 (February 11, 2011), 76 FR 9386 (February 17, 2011) (SR–FINRA–2009–090) (order approving FINRA Rule 5320, ''Prohibition Against Trading Ahead of Customer Orders''). Other exchanges have adopted substantially similar rules prohibiting trading ahead of customer orders. *See, e.g.,* Securities Exchange Act Release No. 64418 (May 6, 2011), 76 FR 27735 (May 12, 2011) (SR–CHX–2011–008) (notice of filing and immediate effectiveness of proposed rule change of Chicago Stock Exchange, Inc. to adopt customer order protection language consistent with FINRA Rule 5320); Securities Exchange Act Release No. 65165 (August 18, 2011), 76 FR 53009 (August 24, 2011) (SR–NYSEAmex–2011–059) (notice of filing and immediate effectiveness of proposed rule change of NYSE Amex LLC (now known as NYSE MKT LLC) to adopt customer order protection language that is substantially the same as FINRA Rule 5320); and Securities Exchange Act Release No. 65166 (August 18, 2011), 76 FR 53012 (August 24, 2011) (SR–NYSEArca–2011–057) (notice of filing and immediate effectiveness of proposed rule change of NYSE Arca, Inc. to adopt customer order protection language that is substantially the same as FINRA Rule 5320).

[6] *See* Securities Exchange Act Release No. 65895 (December 5, 2011), 76 FR 77042 (December 9,

Rule 53.2—Prohibition Against Trading Ahead of Customer Orders

The proposed rule change would replace in its entirety the text of current Rule 53.2 and add a number of exceptions. Proposed Rule 53.2 includes customer order protection language that states if a Trading Permit Holder holds an order in an equity security from its own customer or a customer of another broker-dealer, the Trading Permit Holder is prohibited from trading that security on the same side of the market for its own account at a price that would satisfy the customer order. The proposed rule change states that this prohibition does not apply if a Trading Permit Holder, who has traded proprietarily ahead of a customer order, immediately thereafter executes the customer order up to the size and at the same or better price at which it traded for its own account. In other words, in the event that a Trading Permit Holder trades ahead of an unexecuted customer order at a price that is equal to or better than the unexecuted customer order on the CBSX System, the Trading Permit Holder is required to execute the customer order at the price received by the Trading Permit Holder or better; otherwise the Trading Permit Holder will be in violation of improperly trading ahead of the customer order.[7] The proposed rule change also would establish the minimum amount of price improvement necessary for a Trading Permit Holder to execute an order on a proprietary basis when holding an unexecuted limit order.[8]

The Exchange proposes to establish that a Trading Permit Holder must have written procedures in place governing the execution and priority of all pending orders that is consistent with proposed Rule 53.2 and the best execution requirements of proposed Rule 53.8 and must ensure that these procedures are applied consistently.

In furtherance of ensuring customer order protection, the proposed rule change clarifies Trading Permit Holder obligations in handling marketable customer orders. In meeting these obligations, a Trading Permit Holder must make every effort to execute a marketable customer order that it receives fully and promptly. A Trading Permit Holder that is holding a customer order that is marketable and has not been immediately executed must make every effort to cross the order with any other order received by the Trading Permit Holder on the other side of the market up to the size of such order at a price that is no less than the best bid and no greater than the best offer at the time that the subsequent order is received by the Trading Permit Holder and that is consistent with the terms of the orders. In the event that a Trading Permit Holder is holding multiple orders on both sides of the market that have not been executed, the Trading Permit Holder must make every effort to cross or otherwise execute these orders in a manner that is reasonable and consistent with the objectives of the proposed rule change and with the terms of the orders. A Trading Permit Holder can satisfy the crossing requirement by contemporaneously buying from the seller and selling to the buyer at the same price.[9]

Large Orders and Institutional Accounts Exception [10]

One exception to the prohibition on trading ahead of customer orders permits Trading Permit Holders to negotiate terms and conditions on the acceptance of certain large-sized orders (orders of 10,000 shares or more and greater than or equal to $100,000 in value) or orders from institutional accounts.[11] These terms and conditions will permit Trading Permit Holders to continue to trade alongside or ahead of these customer orders if the customer agrees. A Trading Permit Holder will be permitted to trade a security on the same side of the market for its own account at a price that will satisfy a customer order provided that the Trading Permit Holder provides clear and comprehensive written disclosure to each customer at account opening and annually thereafter that: (1) Discloses that the Trading Permit Holder may trade proprietarily at prices that would satisfy the customer order, and (2) provides the customer with a meaningful opportunity to opt in to the Rule 53.2 protections with respect to all or any portion of its order(s).

If a customer does not opt in to the Rule 53.2 protections with respect to all or any portion of its order(s), the Trading Permit Holder may reasonably conclude that the customer has consented to the Trading Permit Holder trading a security on the same side of the market for its own account at a price that will satisfy the customer's order.[12]

In lieu of providing written disclosure to customers at account opening and annually thereafter, proposed Rule 53.2 will permit Trading Permit Holders to provide clear and comprehensive oral disclosure to, and obtain consent from, a customer on an order-by-order basis, provided that the Trading Permit Holder documents who provided that consent and that the consent evidences the customer's understanding of the terms and conditions of the order. In addition, where a customer has opted in to the Rule 53.2 protections, a Trading Permit Holder may still obtain consent on an order-by-order basis to trade ahead of or along with an order from that customer, provided that the Trading Permit Holder documents who provided the consent and that the consent evidences the customer's understanding of the terms and conditions of the order.[13]

No-Knowledge Exception [14]

The Exchange also proposes to add a ''no-knowledge'' exception to CBSX's

2011) (SR–FINRA–2011–052) (order approving FINRA Rule 5310, ''Best Execution and Interpositioning''). Other exchanges have similar best execution and interpositioning rules. *See, e.g.,* NASDAQ Stock Market LLC Rule 2320 (Best Execution and Interpositioning) and IM–2320; and NASDAQ OMX PHLX LLC Rule 764 (Best Execution and Interpositioning).

[7] For example, if a Trading Permit Holder buys 100 shares of a security at $10 per share while holding customer limit orders in the same security to buy at $10 per share equaling, in aggregate, 1000 shares, the Trading Permit Holder is required to fill 100 shares of the customer limit orders at $10 per share or better.

[8] *See* proposed Rule 53.2, Interpretation and Policy .05. For example, for customer limit orders priced greater than or equal to $1.00, the minimum amount of price improvement required would be $0.01.

[9] *See* proposed Rule 53.2, Interpretation and Policy .06.

[10] *See* proposed Rule 53.2, Interpretation and Policy .01.

[11] Proposed Rule 53.2, Interpretation and Policy .01 defines ''institutional account'' as an account of: (a) A bank, savings and loan association, insurance company, or registered investment company; (b) an investment adviser registered either with the Commission under Section 203 of the Investment Advisers Act of 1940 or with a state securities commission (or any agency or office performing like functions); or (c) any other entity (whether a natural person, corporation, partnership, trust, or otherwise) with total assets of at least $50 million.

[12] As is always the case, customers retain the right to withdraw consent at any time. Therefore, a Trading Permit Holder's reasonable conclusion that a customer has consented to the Trading Permit Holder trading along with the customer's order is subject to further instruction and modification from the customer.

[13] While a Trading Permit Holder organization relying on this or any exception must be able to proffer evidence of its eligibility for and compliance with the exception, the Exchange believes that when obtaining consent on an order-by-order basis, Trading Permit Holders must, at a minimum, document not only the terms and conditions of the order (*e.g.,* the relative price and size of the allocated order/percentage split with the customer), but also the identity of the person at the customer who approved the trade-along request. For example, the identity of the person must be noted in a manner that will enable subsequent contact with that person if a question as to the consent arises (*i.e.,* first names only, initials, and nicknames will not suffice). A ''trade along'' request would be when a Trading Permit Holder asks to trade for his/her proprietary account while simultaneously holding and working a customer order in that same stock.

[14] *See* proposed Rule 53.2, Interpretation and Policy .02.

customer order protection rule. This proposed exception will allow a proprietary trading unit of a Trading Permit Holder organization to continue trading in a proprietary capacity and at prices that will satisfy customer orders that are being held by another, separate trading unit at the Trading Permit Holder organization. The ''no-knowledge'' exception will be applicable with respect to NMS stocks, as defined in Rule 600 of SEC Regulation NMS. In order to avail itself of the ''no-knowledge'' exception, a Trading Permit Holder organization will first be required to implement and utilize an effective system of internal controls (such as appropriate information barriers) that operate to prevent the proprietary trading unit from obtaining knowledge of the customer orders that are held at a separate trading unit. For example, in the case of a CBSX Broker [15] that conducts both a proprietary and agency brokerage business and has implemented and utilized an effective system of internal controls, the ''walled off'' proprietary desk(s) of the CBSX Broker will be permitted to trade at prices that will satisfy the customer orders held by the agency brokerage desk without any requirement that these proprietary executions trigger an obligation to fill pending customer orders at the same price. The ''no-knowledge'' exception will also apply to a Trading Permit Holder organization's market-making unit.

A Trading Permit Holder organization that structures its order handling practices in NMS stocks to permit its proprietary and/or market-making desk to trade at prices that will satisfy customer orders held by a separate trading unit must disclose in writing to its customers, at account opening and annually thereafter, a description of the manner in which customer orders are handled by the Trading Permit Holder and the circumstances under which the Trading Permit Holder may trade proprietarily at its market-making desk at prices that will satisfy the customer order. This proposed disclosure may be combined with the disclosure and negative consent statement permitted in connection with the proposed large order and institutional account exceptions.

If a Trading Permit Holder intends to rely on the no-knowledge exception by implementing information barriers, those information barriers must (1) provide for the organizational separation of a Trading Permit Holder's trading unit that holds customer orders and a proprietary trading unit; (2) ensure that one trading unit does not exert influence over the other trading unit; (3) ensure that information relating to each trading unit's stock positions, trading activities, and clearing and margin arrangements is not improperly shared (except with persons in senior management who are involved in exercising general managerial oversight of one or both entities); (4) require each trading unit to maintain separate books and records (and separate financial accounting); (5) require each trading unit to separately meet all required capital requirements; (6) ensure the confidentiality of each trading unit's book as provided by Exchange rules; and (7) ensure that any other material, non-public information (*e.g.,* information related to any business transactions between a trading unit and an issuer or any research reports or recommendations issued by the trading unit) is not made improperly available to the other trading unit in any manner that will allow that trading unit to take undue advantage of that information while trading on CBSX. A Trading Permit Holder will be required to submit the proposed information barriers in writing to the Exchange upon request.

The proposed rule change requires Trading Permit Holders that intend to rely on the no-knowledge exception by implementing information barriers to have ''appropriate'' information barriers. The Exchange stated its belief that including these specific information barrier requirements will clarify for Trading Permit Holders the types of information barriers that will be deemed appropriate information barriers and thus better allow Trading Permit Holders to rely on this exception. The Exchange noted that its surveillance procedures will continue to include a review of all orders for compliance with the prohibition on trading ahead of customer orders, and part of that review will include review of Trading Permit Holders' information barriers to determine whether they are sufficient for Trading Permit Holders to avail themselves of the no-knowledge exception for each applicable order. These requirements regarding information barriers are substantially similar to those set forth in CBOE Rule 54.8, which includes special provisions for trading commodity-based trust shares on CBSX, except that the proposed rule change provides that information barriers must be submitted upon request while CBOE Rule 54.8 provides that information barriers must be submitted and approved in advance. The Exchange stated its belief that it is appropriate and efficient to request from a Trading Permit Holder its information barriers as part of its surveillance procedures with respect to the customer order protection rule.

ISO Exception[16]

The proposed rule change also clarifies that a Trading Permit Holder will be exempt from the obligation to execute a customer order in a manner consistent with CBSX's customer order protection rule with regard to trading for its own account that is the result of an intermarket sweep order routed in compliance with Regulation NMS (''ISO'') [17] where the customer order is received after the Trading Permit Holder routed the ISO. Where a Trading Permit Holder routes an ISO to facilitate a customer order and that customer has consented to not receiving the better prices obtained by the ISO, the Trading Permit Holder also will be exempt with respect to any trading for its own account that is the result of the ISO with respect to the consenting customer's order.

Odd Lot and Bona Fide Error Transaction Exception [18]

The Exchange proposes applying an exception for a firm's proprietary trade that (1) offsets a customer odd lot order (*i.e.,* an order less than one round lot, which is typically 100 shares); or (2) corrects a bona fide error. With respect to bona fide errors, Trading Permit Holder will be required to demonstrate and document the basis upon which a transaction meets the bona fide error exception. For purposes of this proposed Rule, the definition of a ''bona fide error'' is as defined in Regulation NMS's exemption for error correction transactions.[19]

Trading Outside Normal Market Hours [20]

The proposed rule change will expand CBSX's customer order protection requirements to apply at all times that a customer order is executable by the Trading Permit Holder, even outside the period of normal market hours. Thus, customers

[15] A ''CBSX Broker'' is a Trading Permit Holder who enters orders as an agent. *See* Rule 50.3(5).

[16] *See* proposed Rule 53.2, Interpretation and Policy .03.

[17] 17 CFR 242.600(b)(30)(ii).

[18] *See* proposed Rule 53.2, Interpretation and Policy .04.

[19] *See* Securities Exchange Act Release No. 55884 (June 8, 2007), 72 FR 32926 (June 14, 2007) (Order Exempting Certain Error Correction Transactions from Rule 611 of Regulation NMS under the Securities Exchange Act of 1934).

[20] *See* proposed Rule 53.2, Interpretation and Policy .07.

will have the benefit of the customer order protection rules at all times where such order is executable by the Trading Permit Holder, subject to any applicable exceptions. This exception will apply to those Trading Permit Holders that accept customer orders after normal market hours.

Rule 53.8—Best Execution and Interpositioning

The Exchange also proposes to adopt a new rule to govern Trading Permit Holders' best execution and interpositioning requirements. Proposed Rule 53.8(a)(1) will require a Trading Permit Holder or person associated with a Trading Permit Holder, in any transaction for or with a customer or a customer of another broker-dealer, to use ''reasonable diligence'' to ascertain the best market for a security and to buy or sell in that market so that the resultant price to the customer is as favorable as possible under prevailing market conditions. The proposed rule identifies five factors that are among those to be considered in determining whether the Trading Permit Holder or person associated with a Trading Permit Holder has used reasonable diligence:

(1) The character of the market for the security;

(2) the size and type of transaction;

(3) the number of markets checked;

(4) the accessibility of the quotation; and

(5) the terms and conditions of the order as communicated to the Trading Permit Holder or person associated with the Trading Permit Holder.

Proposed Rule 53.8(a)(2) relates to interpositioning and prohibits a Trading Permit Holder or person associated with a Trading Permit Holder, in any transaction for or with a customer or a customer of another broker-dealer, from interjecting a third party between the Trading Permit Holder or person associated with a Trading Permit Holder and the best market for the subject security in a manner inconsistent with the best execution requirements in subparagraph (a)(1) of proposed Rule 53.8.

Proposed Rule 53.8 also includes provisions related to the use of a broker's broker, the staffing of order rooms, and the application of the best execution requirements to other parties. Proposed paragraph (b) provides that when a Trading Permit Holder cannot execute directly with a market but must employ a broker's broker or some other means in order to ensure an execution advantageous to the customer, the burden of showing the acceptable circumstances for doing so is on the Trading Permit Holder. Proposed paragraph (c) provides that failure to maintain or adequately staff a department assigned to execute customers' orders cannot be considered justification for executing away from the best available market; nor can channeling orders through a third party as reciprocation for service or business operate to relieve a Trading Permit Holder of its obligations under proposed Rule 53.8. Proposed paragraph (d) provides that a Trading Permit Holder through which an order is channeled and that knowingly is a party to an arrangement whereby the initiating Trading Permit Holder has not fulfilled its obligations under Rule 53.8 will also be deemed to have violated Rule 53.8. Proposed paragraph (e) provides that the obligations in paragraphs (a) through (d) apply when the Trading Permit Holder acts as agent for the account of its customer as well as when transactions are executed as principal.

Proposed Rule 53.8 includes several Interpretations and Policies to provide additional guidance and clarity regarding Trading Permit Holders' obligations with respect to the best execution and interpositioning requirements. Proposed Interpretation and Policy .01 reinforces a Trading Permit Holder's duty to make every effort to execute a marketable customer order that it receives fully and promptly. Proposed Interpretation and Policy .02 defines the term ''market'' for the purposes of proposed Rule 53.8.[21]

Proposed Interpretation and Policy .03 addresses broker-dealers that are executing a customer's order against the Trading Permit Holder's quote. It provides that a Trading Permit Holder's duty to provide best execution in any transaction ''for or with a customer of another broker-dealer'' does not apply in instances when another broker-dealer is simply executing a customer order against the Trading Permit Holders' quote. The duty to provide best execution to customer orders received from other broker-dealers arises only when an order is routed from the broker-dealer to the Trading Permit Holder for the purpose of order handling and execution. This clarification is intended to draw a distinction between those situations in which the Trading Permit Holder is acting solely as the buyer or seller in connection with orders presented by a broker-dealer against the Trading Permit Holder's quote, as opposed to those circumstances in which the Trading Permit Holder is accepting order flow from another broker-dealer for the purpose of facilitating the handling and execution of such orders.

Proposed Interpretation and Policy .04 provides that when a Trading Permit Holder cannot execute directly with a market but must employ a broker's broker or some other means in order to ensure an execution advantageous to the customer, the burden of showing the acceptable circumstances for doing so is on the Trading Permit Holder. Examples of acceptable circumstances are where a customer's order is crossed with another firm that has a corresponding order on the other side, or where the identity of the firm, if known, would likely cause undue price movements adversely affecting the cost or proceeds to the customer.

Proposed Interpretation and Policy .05 addresses the fact that markets for securities differ dramatically and provides additional guidance regarding a Trading Permit Holder's best execution obligations when handling an order involving any security for which there is limited pricing information or other quotations available. The Interpretation and Policy emphasizes that Trading Permit Holders must be especially diligent with respect to best execution obligations where there is limited quotation or other pricing information available regarding the security that is the subject of the order and requires Trading Permit Holders to have written policies and procedures in place to address the steps the Trading Permit Holder will take to determine the best interdealer market for such a security in the absence of multiple quotations or pricing information and to document how they have complied with those policies and procedures. The Interpretation and Policy specifically notes that, when handling orders for these securities, Trading Permit Holders should generally seek out other sources of pricing information or potential liquidity, which may include obtaining quotations from other sources (*e.g.,* other firms that the Trading Permit Holder previously has traded within the security). For example, in many instances, particularly in the context of equity securities with limited quotation information available, contacting other broker-dealers may be necessary to

[21] For purposes of proposed Rule 53.8 and the accompanying Interpretations and Policies, the term ''market'' or ''markets'' is to be construed broadly, and it encompasses a variety of different venues, including, but not limited to, market centers that are trading a particular security. This expansive interpretation is meant to both inform broker-dealers as to the breadth of the scope of venues that must be considered in the furtherance of their best execution obligations and to promote fair competition among broker-dealers, exchange markets, and markets other than exchange markets, as well as any other venue that may emerge, by not mandating that certain trading venues have less relevance than others in the course of determining a firm's best execution obligations.

comply with a Trading Permit Holder's best execution obligations.

When placing an order with a Trading Permit Holder, customers may specifically instruct the Trading Permit Holder to route the order to a particular market for execution.[22] Proposed Interpretation and Policy .06 addresses situations where the customer has, on an unsolicited basis, specifically instructed the Trading Permit Holder to route that customer's order to a particular market for execution.[23] Under those circumstances, the Trading Permit Holder will not be required to make a best execution determination beyond that specific instruction; however, the Interpretation and Policy mandates that Trading Permit Holders process that customer's order promptly and in accordance with the terms of the order. The Interpretation and Policy also makes clear that where a customer has directed the Trading Permit Holder to route an order to another specific broker-dealer that is also a Trading Permit Holder, the exception will not apply to the receiving Trading Permit Holder to which the order was directed.[24]

Proposed Interpretation and Policy .07 codifies a Trading Permit Holder's obligation when it undertakes a regular and rigorous review of execution quality likely to be obtained from different market centers. These obligations are set forth and explained in various Commission releases and NASD *Notices to Members.*[25]

III. Commission's Findings

After careful review of the proposed rule change the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to self-regulatory organization.[26] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[27] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, 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 believes that the proposed rule change is designed to protect customer orders by establishing requirements governing the trading ahead of customer orders by member firms and governing best execution and interpositioning with respect to the handling of customer orders. By CBOE aligning its customer protection rules with those of FINRA and other exchanges,[28] the Commission believes that the proposed rule change will help reduce the complexity of the customer order protection rules for those CBOE firms that also are subject to the customer protection rules of FINRA and other exchanges. Furthermore, the Commission believes that the proposed rules will help assure the protection of customer orders without imposing undue regulatory costs on industry participants.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[29] that the proposed rule change (SR–CBOE–2013–027), as modified by Amendment No. 1, be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

Kevin M. O'Neill,

Deputy Secretary.

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[22] When the order is for an NMS security, these orders are often referred to as ''directed orders.'' *See* 17 CFR 242.600(b)(19). Of note, directed orders are excluded from the order routing statistics required to be produced under Rule 606 of SEC Regulation NMS. *See* 17 CFR 242.606.

[23] The Interpretation and Policy also clarifies that a Trading Permit Holder's best execution obligations extend to all customer orders and is intended to avoid the potential misimpression that the paragraph limits the scope of the rule's requirements.

[24] For example, if a customer of Trading Permit Holder Firm A directs Trading Permit Holder Firm A to route an order to Trading Permit Holder Firm B, Trading Permit Holder Firm B will continue to have best execution obligations to that customer order received from Trading Permit Holder Firm A.

[25] *See, e.g.,* Securities Exchange Act Release No. 37619A (September 6, 1996), 61 FR 48290 (September 12, 1996) and NASD Notice to Members 01–22 (April 2001).

[26] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[27] 15 U.S.C. 78f(b)(5).

[28] *See* notes 5 and 6 *supra.*

[29] 15 U.S.C. 78s(b)(2).

[30] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69495; File No. SR–FICC–2013–04]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing of Proposed Rule Change to the Government Securities Division Rules and the Mortgage-Backed Securities Division Clearing Rules in Connection With the Implementation of the Foreign Account Tax Compliance Act (FATCA)

May 2, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 22, 2013, the Fixed Income Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been substantially prepared by FICC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule changes consist of modifications to the Rulebook of the Government Securities Division (''GSD'') and the Clearing Rules of the Mortgage-Backed Securities Division (''MBSD'') (collectively, the ''Rules'') of FICC in connection with implementation of sections 1471 through 1474 of the Internal Revenue Code of 1986, as amended, that were enacted as part of the Foreign Account Tax Compliance Act, and the Treasury Regulations or other official interpretations thereunder (collectively ''FATCA'').

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FICC 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. FICC has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.[3]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission has modified the text of the summaries prepared by the clearing agency.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Background

FATCA was enacted on March 18, 2010, as part of the Hiring Incentives to Restore Employment Act, and became effective, subject to transition rules, on January 1, 2013. The U.S. Treasury Department finalized and issued various implementing regulations (''FATCA Regulations'') on January 17, 2013. FATCA's intent is to curb tax evasion by U.S. citizens and residents through their use of offshore bank accounts. FATCA generally requires foreign financial institutions (''FFIs'')[4] to become ''participating FFIs'' by entering into agreements with the Internal Revenue Service (''IRS''). Under these agreements, FFIs are required to report to the IRS information on U.S. persons and entities that have (directly or indirectly) accounts with these FFIs. If an FFI does not enter into such an agreement with the IRS, FATCA will impose a 30% withholding tax on U.S.-source interest, dividends and other periodic amounts paid to such ''nonparticipating FFI'' (''Income Withholding''), as well as on the payment of gross proceeds arising from the sale, maturity or redemption of securities or any instrument yielding U.S.-source interest and dividends (''Gross Proceeds Withholding,'' and, together with Income Withholding, ''FATCA Withholding''). The 30% FATCA Withholding taxes will apply to payments made to a nonparticipating FFI acting in any capacity, including payments made to a nonparticipating FFI that is not the beneficial owner of the amount paid and acting only as a custodian or other intermediary with respect to such payment. To the extent that U.S.-source interest, dividend, and other periodic amount or gross proceeds payments are due to a nonparticipating FFI in any capacity, a U.S. payor, such as FICC, transmitting such payments to the nonparticipating FFI will be liable to the IRS for any amounts of FATCA Withholding that the U.S. payor should, but does not, withhold and remit to the IRS. For the reasons described below, FICC is not in a position to accept this liability and, by making the proposed rule changes set forth herein, is implementing preventive measures to protect itself against such liability.

In addition, under FATCA, a U.S. payor, such as FICC, could be required to deduct Income Withholding with regard to a participating FFI if either: (x) the participating FFI makes a statutory election to shift its withholding responsibility under FATCA to the U.S. payor; or (y) the U.S. payor is required to ignore the actual recipient and treat the payment as if made instead to certain owners, principals, customers, account holders or financial counterparties of the participating FFI. FICC is not in a position to accept this burden shift and, by making the proposed rule changes set forth herein, is implementing preventive measures to protect itself against such a burden.

As an alternative to FFIs entering into individual agreements with the IRS, the U.S. Treasury Department provided another means of complying with FATCA for FFIs which are resident in Non-U.S. jurisdictions that enter into intergovernmental agreements (''IGA'') with the United States.[5] Generally, such a jurisdiction (''FATCA Partner'') would pass laws to eliminate the conflicts of law issues that would otherwise make it difficult for FFIs in its jurisdiction to collect the information required under FATCA and transfer this information, directly or indirectly, to the United States. An FFI resident in a FATCA Partner jurisdiction would either transmit FATCA reporting to its local competent tax authority, which in turn would transmit the information to the IRS, or the FFI would be authorized/required by FATCA Partner law to enter into an FFI agreement and transmit FATCA reporting directly to the IRS. Under both IGA models, payments to such FFIs would not be subject to FATCA Withholding so long as the FFI complies with the FATCA Partner's laws mandated in the IGA.

Under the FATCA Regulations, (A) beginning January 1, 2014, FICC will be required to do Income Withholding on any payments made to any nonparticipating FFI approved for membership by FICC as of such date or thereafter, (B) beginning July 1, 2014, FICC will be required to do Income Withholding on any payments made to any nonparticipating FFI approved for membership by FICC prior to January 1, 2014 and (C) beginning January 1, 2017, FICC will be required to do Gross Proceeds Withholding on all nonparticipating FFIs, regardless when any such FFI's membership was approved.

Preparing for Implementation of FATCA

In preparation for FATCA's implementation, FFIs are being asked to identify their expected FATCA status as a condition of continuing to do business. Customary legal agreements in the financial services industry already contain provisions allocating the risk of any FATCA Withholding tax that will need to be collected, and requiring that, upon FATCA's effectiveness, foreign counterparties must certify (and periodically recertify) their FATCA status using the relevant tax forms that the IRS has announced it will provide.[6] Advance disclosure by an FFI client or counterparty would permit a withholding agent to readily determine whether it must, under FATCA, withhold on payments it makes to the FFI. If an FFI fails to provide appropriate compliance documentation to a withholding agent, such FFI would be presumed to be a nonparticipating FFI and the withholding agent will be obligated to withhold on certain payments.

As it applies to FICC specifically, FATCA will require FICC to deduct FATCA Withholding on payments to certain members arising from certain transactions processed by FICC on behalf of such members.[7] Because FATCA treats any entity holding financial assets for the account of others as a ''financial institution,'' FICC believes that almost all of its members which are treated as non-U.S. entities for federal income tax purposes, including those members that are U.S. branches of non-U.S. entities, will likely be FFIs under FATCA (collectively, ''FFI Members'').[8] As such, FICC will be liable to the IRS for any failures to withhold correctly under FATCA on payments made to its FFI Members.

In light of this, FICC has evaluated its existing systems and services to determine whether and how it may comply with its FATCA obligations. As a result of this evaluation, FICC has determined that its existing systems currently cannot process the new FATCA Withholding obligations with regard to the securities transactions processed by it, as no similar withholding obligation of this

[4] Non-U.S. financial institutions are referred to as ''foreign financial institutions'' or ''FFIs'' in the FATCA Regulations.

[5] As of the date of this proposed rule change filing, the United Kingdom, Mexico, Ireland, Switzerland, Spain, Norway Denmark, Italy and Germany have signed or initialed an IGA with the United States. The U.S. Treasury Department has announced that it is engaged in negotiations with more than 50 countries and jurisdictions regarding entering into an IGA.

[6] For example, credit agreements now routinely require foreign lenders to agree to provide certifications of their FATCA status under approved IRS forms to U.S. borrowers, and subscription agreements for alternative investment funds that are anticipated to earn U.S.-source income are routinely requiring similar covenants.

[7] FFI Members resident in IGA countries, that are compliant with the terms of applicable IGAs, should not be subject to FATCA Withholding.

[8] Currently, only a small percentage of the Corporation's members are treated as non-U.S. entities for federal income tax purposes.

magnitude has ever been imposed upon it to date, and FICC has therefore not built its systems to support such an obligation.

Further, the vast majority of the transactions that are processed at FICC are processed through its netting and settlement systems at its GSD and MBSD divisions (the ''Systems''). At GSD, the netting and settlement system service provides centralized, automated clearance and guaranteed settlement of eligible U.S. Treasury bills, notes, bonds, strips and book-entry non-mortgage-backed agency securities. Through netting, the GSD establishes a single net long or short position for each participant's daily trading activity in a given security. The participant's net position is the difference between all long and all short positions in a given security.

At MBSD, the mortgage-backed securities trades entering the MBSD clearing and settlement systems are settled using either the Settlement Balance Order system (SBO) or the Trade-for-Trade system (TFTD). The SBO settlement system is MBSD's trade netting system, which nets by automatically pairing off settlement obligations with like terms, such as MBS product, coupon rate, maturity and settlement date, on a multilateral basis, i.e., regardless of contra party identity, resulting in the fewest possible number of receive/deliver obligations. Through the Trade-for-Trade settlement system, members are given the opportunity to settle individual trades on a gross basis, as originally executed, following matching and comparison of each trade. Further netting is accomplished through MBSD's CCP Pool Netting service (''Pool Netting''). Members submit pool details (''Pool Instructs'') into the Pool Netting system for bilateral matching versus their counterparties' submissions. As many of the matched Pool Instructs as possible are then netted by the Pool Netting system. For pools that meet all the criteria, FICC steps in as the central counter-party to settle the net pool obligations with its members.

FICC believes that each division's net settlement functionality could make FATCA Withholding virtually impossible, or, at the very least, would create onerous efficiency and liquidity issues for both FICC and its membership. Undertaking FATCA Withholding, given FICC's settlement functionality, could require FICC in certain circumstances to resort to a draw on FICC's clearing fund for GSD or MBSD, as applicable (''Clearing Fund'') in order to fund FATCA Withholding taxes with regard to nonparticipating FFI Members in non-FATCA Partner jurisdictions whenever the net credit owed to such FFI Member is less than the 30% FATCA tax. For example, if a nonparticipating FFI (in a non-FATCA Partner jurisdiction) is owed a $100M payment from the sale of U.S. securities, but such nonparticipating FFI is in a net debit position at the end of that day because of FICC's net settlement functionality, there would be no payment to this FFI Member from which FICC can withhold. In this example, FICC would likely need to fund the $30M FATCA Withholding tax until such time as the FFI Member can reimburse FICC and, as FICC has no funds for this purpose, it would likely require a draw on the Clearing Fund.[9] FICC would need to consider an increase in the amount of cash required to be deposited into the Clearing Fund, either by FFI Members or perhaps all of its members, which would reduce such member's liquidity and could have significant systemic effects. The amount of the FATCA Withholding taxes would be removed from market liquidity, which could lead to increased risk of member failure and increased financial instability.

For the reasons explained above and the following additional reasons, FICC is proposing amendments to its Rules (detailed below) to implement preventive measures that would generally require all of FICC's (i) existing members that are treated as Non-U.S. entities for federal income tax purposes and (ii) any applicants applying to become members that are treated as Non-U.S. entities for federal income tax purposes to be participating FFIs:

- Undertaking FATCA Withholding by FICC (even if possible) would make it economically unfeasible for affected FFI Members to engage in transactions involving U.S. securities. It would likely also quickly cause a significant negative impact on such FFI Members' liquidity because such withholding taxes would be imposed on the very large sums that FICC pays to such FFI Members. Furthermore, members would be burdened with extra costs and the negative impact on liquidity caused by the likely need to substantially increase the amount of cash required to be deposited into the Clearing Fund.
- The cost of implementing a FATCA Withholding system for a small number of nonparticipating FFI Members would be substantial and disproportionate to the related benefit. Under the Model I IGA form and its executed versions with various FATCA Partners, FICC would not be required to withhold with regard to FFI residents in such FATCA Partner jurisdictions. Accordingly, FICC's withholding obligations under FATCA would effectively be limited to nonparticipating FFI Members in non-FATCA Partner jurisdictions. Since the cost of developing and maintaining a complex FATCA Withholding system would be passed on to FICC's members at large, it may burden members that otherwise comply with, or are not subject to, FATCA Withholding.
- As briefly noted above, if the proposed rule changes were not to take effect, in order to avoid counterparty credit risk, FICC would likely require each of the nonparticipating FFI Members in non-FATCA Partner jurisdictions to make initial or additional cash deposits to the Clearing Fund as collateral for the approximate potential FATCA tax liability of such nonparticipating FFI Member or otherwise adjust required deposits to the Clearing Fund. The amount of such deposits, which could amount to billions of dollars, would be removed from market liquidity.
- From the nonparticipating FFI Member's perspective, having 30% of its payments withheld and sent to the IRS would have a severe negative impact on such nonparticipating FFI Member's financial status. In many cases, the gross receipts would be for client accounts, and the nonparticipating FFI Member would need to make such accounts whole. Without receipt of full payment for its dispositions, the nonparticipating FFI Member would not have sufficient assets to fund its client accounts.
- The proposed rule changes set forth herein should not create business issues or be onerous to FICC's membership because requiring FFIs to certify (and to periodically recertify) their FATCA status, and imposing the costs of non-compliance on them, are becoming standard market practice in the United States, separate and apart from membership in FICC.

Proposed Rule Changes

Managing the risks inherent in executing securities transactions is a key component of FICC's business. The globalization of financial markets, the

[9] We note that the FATCA Regulations provide that ''clearing organizations'', which settle money on a net basis, may withhold on a similar net basis for FATCA purposes. However, it is unclear whether certain amounts being netted at the Corporation would qualify for the special FATCA netting rule. Even if the end of day net settlement amount would qualify as the correct amount to do FATCA Withholding on, the liquidity risks described herein are still present. This is because the sheer volume of the Corporation's net daily payments among the Corporation and members means that withholding FATCA tax from such net settlement payments, in any material proportion, would likely reduce liquidity and thus increase financial instability.

trading of more complex instruments and the application of new technology all make risk management more critical and challenging. FICC's ''risk tolerances'' (i.e., the levels of risk FICC is prepared to confront, under a range of possible scenarios, in carrying out its business functions) are determined by the Board of Directors, in consultation with the Group Chief Risk Officer. FICC uses a combination of risk management tools, including strict criteria for membership, to mitigate the risks inherent in its business.

In line with its risk management focus, FICC has determined that compliance with FATCA, such that FICC shall not be responsible for FATCA Withholding, should be a general membership requirement (A) for all applicants seeking membership at GSD or MBSD, as applicable, that are treated as non-U.S. entities for federal income tax purposes, and (B) for all existing FFI Members.[10] In connection therewith, FICC proposes to amend its Rules as follows:

- Amend GSD Rule 1 and MBSD Rule 1 to add ''FATCA'', ''FATCA Certification'', ''FATCA Compliance Date''[11], ''FATCA Compliant'' and ''FFI Member'', as defined terms;
- Amend GSD Rule 2A, Section 2(a)(v) and MBSD Rule 2A, Section 1 to (1) require foreign members to certify to FICC that they are FATCA Compliant and (2) add FATCA Compliance as a qualification requirement for any applicant that will be an FFI Member;
- Amend GSD Rule 2A Section 5 and MBSD Rule 2A Section 3 to add that each applicant must complete and deliver a FATCA Certification to FICC as part of its membership application unless FICC has waived this requirement with regard to membership type;
- Amend GSD Rule 2A Section 6 and MBSD Rule 2A Section 4 to add FATCA Compliance as a qualification requirement for any applicant that will be an FFI Member;
- Amend GSD Rule 3, Section 7 and MBSD Rule 3, Section 6 to specify that failure to be FATCA Compliant creates a duty upon an FFI Member (both new and existing) to inform FICC;
- Amend GSD Rule 3, Section 9 and MBSD Rule 3, Section 8 to require that all FFI Members (both new and existing), in general: (i) Agree not to conduct any transaction or activity through FICC if such FFI Member is not FATCA Compliant, (ii) certify and, as required under the timelines set forth under FATCA, periodically recertify, to FICC that they are FATCA Compliant; and (iii) indemnify FICC for any losses sustained by FICC resulting from such FFI Member's failure to be FATCA Compliant.
- FICC believes the proposed rule changes are consistent with the requirements of the Exchange Act. In particular, the proposed rule changes are consistent with Section 17A(b)(3)(F) of the Exchange Act[12] because they promote the prompt and accurate clearing and settlement of securities transactions by eliminating an uncertainty in payment settlement that would arise if FICC were subject to FATCA Withholding obligations under FATCA. The proposed rule changes are also consistent with Section 17A(b)(3)(D) of the Exchange Act[13] because they provide for the equitable allocation of reasonable dues, fees, and other charges among FICC's members. Specifically, the proposed rule changes allow FICC to comply with FATCA Regulations without developing and maintaining a complex FATCA Withholding system, the cost of which, as discussed above, would be would be passed on to FICC's members at large for the benefit of a small number of nonparticipating FFI Members.

(B) Clearing Agency's Statement on Burden on Competition

FICC does not believe that the proposed rule change will have any negative impact, or impose any burden, on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Written comments relating to the proposed rule changes have not yet been solicited or received. FICC will notify the Commission of any written comments received by FICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Exchange 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–FICC–2013–04 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FICC–2013–04. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of FICC and on FICC's Web site (*http://www.dtcc.com/legal/rule_filings/*

[10] FICC may grant a waiver under certain circumstances, provided, however, that FICC will not grant a waiver if it causes FICC to be obligated to withhold under FATCA on gross proceeds from the sale or other disposition of any property.

[11] Although Income Withholding with regard to FFI Members approved for membership by the Corporation prior to January 1, 2014 is first required under FATCA beginning July1, 2014, the proposed amendments to the GSD Rules and MBSD Rules would require such existing FFI Members to be FATCA compliant approximately 60 days prior to July 1, 2014 in order for the Corporation to comply with its disciplinary and notice processes as set forth in its Rules.

[12] 12 U.S.C. 78q–1(b)(3)(F).

[13] 12 U.S.C. 78q–1(b)(3)(D).

ficc/2013.php). 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–FICC–2013–04 and should be submitted on or before May 29, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–10847 Filed 5–7–13; 8:45 am]

BILLING CODE 8011–01–P

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69503; File No. SR–NYSEArca–2013–44]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Its Schedule of Fees and Charges for Exchange Services To Amend Step Up Tier 2 to Reduce the Volume Threshold Requirements Needed To Be Eligible for The Tier

May 2, 2013.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on April 22, 2013, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Schedule of Fees and Charges for Exchange Services (''Fee Schedule'') to amend Step Up Tier 2 to reduce the volume threshold requirements needed to be eligible for the tier. The Exchange proposes to implement the changes on May 1, 2013. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule to amend Step Up Tier 2 to reduce the volume threshold requirements needed to be eligible for the tier. The Exchange proposes to implement the changes on May 1, 2013.

Currently, in order to qualify for Step Up Tier 2, an ETP Holder on a daily basis, measured monthly, must directly execute providing volume on NYSE Arca in an amount that is an increase of no less than 0.12% of U.S. consolidated average daily volume (''US CADV'') in Tape A, Tape B, and Tape C securities for that month over the ETP Holder's average daily providing volume in June 2011 (the ''Baseline Month''), subject to a minimum increase of 12 million average daily providing shares. The Exchange proposes to reduce the eligibility requirement for Step Up Tier 2 to no less than 0.10% of US CADV for the month over the ETP Holder's average daily providing volume in the Baseline Month, subject to a minimum increase of 10 million average daily providing shares. The Exchange does not propose to amend the credits for Step Up Tier 2.

By way of example, if an ETP Holder executed an average daily providing volume of 5 million shares in the Baseline Month, then to qualify for Step Up Tier 2 in a month where US CADV is 11 billion shares, that ETP Holder would need to increase its average daily providing volume by at least 11 million shares, or 0.10% of that month's US CADV, for a total average daily providing volume of at least 16 million shares.[4]

The Exchange notes that the proposed fee change will reverse the Step Up Tier 2 fee changes that became operative on April 1, 2013.[5] The Exchange is proposing the Step Up Tier 2 fee change because the previous fee change did not result in the anticipated increase in orders sent to the Exchange. As previously explained,[6] the goal of the Step Up Tiers is to incent ETP Holders to increase the orders sent directly to the Exchange and therefore provide liquidity that supports the quality of price discovery and promotes market transparency. In the Step Up Tiers Release, the Exchange explained that the Step Up Tiers were expected to benefit ETP Holders whose increased order flow provided added levels of liquidity (thereby contributing to the depth and market quality on the Exchange) but who are still not eligible for Tier 1, 2 or 3, or Investor Tier 1 or 2.[7] For similar reasons, the Exchange believes that lowering the volume requirements needed to be eligible for Step Up Tier 2 will allow a greater number of ETP Holders to qualify for the tier, which will in turn incent ETP Holders to increase the orders sent directly to the Exchange and therefore provide liquidity that supports the quality of price discovery and promotes market transparency. The Exchange believes that this especially is the case given that the $0.0029 credit for providing liquidity in Tape A and Tape C securities under Step Up Tier 2 is substantially higher than the credits for Tape A and Tape C securities under the Basic Rates ($0.0021) and Tier 3 ($0.0025).

The proposed changes are not otherwise intended to address any other problem, and the Exchange is not aware of any significant problem that the affected market participants would have in complying with the proposed changes.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with

[4] In addition, those ETP Holders that did not directly provide volume to NYSE Arca in the Baseline Month will be treated as having an average daily providing volume of zero for the Baseline Month. With respect to the increased percentage of US CADV, the volume requirements to reach Step Up Tier 2's pricing levels will adjust each calendar month based on the US CADV for that given month.

[5] *See* Securities Exchange Act Release No. 69305 (April 4, 2013), 78 FR 21443 (April 10, 2013) (SR–NYSEArca–2013–32).

[6] *See* Securities Exchange Act Release No. 64820 (July 6, 2011), 76 FR 40974 (July 12, 2011) (SR–NYSEArca–2011–41) (''Step Up Tiers Release'').

[7] *Id.* at 76 FR 40975.

Section 6(b) of the Act,[8] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[9] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed amendment to Step Up Tier 2 that lowers the volume requirements needed to be eligible for the tier is reasonable because the proposed change is designed to further incent ETP Holders to increase the orders sent directly to the Exchange and therefore provide liquidity that supports the quality of price discovery and promotes market transparency. The Exchange believes that this is especially the case given that the $0.0029 credit for providing liquidity in Tape A and Tape C securities is substantially higher than the credits for Tape A and Tape C securities under the Basic Rates ($0.0021) and Tier 3 ($0.0025). In addition, the proposed change is reasonable because it is reverting to the volume thresholds that were previously in place at the Exchange.[10] The Exchange further believes that the proposed amendment is equitable and not unfairly discriminatory because it will allow a greater number of ETP Holders to qualify for the tier, which will in turn incent ETP Holders to increase order flow and provide added levels of liquidity (thereby contributing to the depth and market quality on the Exchange), even if they may not be eligible for Tier 1, 2 or 3, or Investor Tier 1 or 2. Moreover, Step Up Tier 2 is available for all ETP Holders to satisfy.

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. In particular, the proposed amendment to Step Up Tier 2 that lowers the volume requirement needed to be eligible for the tier is designed to incent ETP Holders and Market Makers to increase the volume of orders sent directly to the Exchange and therefore provide liquidity that supports the quality of price discovery and promotes market transparency.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[11] of the Act and subparagraph (f)(2) of Rule 19b–4[12] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

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 under Section 19(b)(2)(B)[13] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2013–44 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2013–44. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR–NYSEArca–2013–44 and should be submitted on or before May 29, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–10902 Filed 5–7–13; 8:45 am]

BILLING CODE 8011–01–P

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(4) and (5).

[10] *See supra* n.5.

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(2).

[13] 15 U.S.C. 78s(b)(2)(B).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69497; File No. SR–NSCC–2013–04]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing of Proposed Rule Change in Connection With the Implementation of the Foreign Account Tax Compliance Act (FATCA)

May 2, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 22, 2013, National Securities Clearing Corporation (''NSCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been substantially prepared by NSCC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change modifies NSCC's Rules and Procedures (''Rules''), as described below, in connection with the implementation of sections 1471 through 1474 of the Internal Revenue Code of 1986, as amended, which sections were enacted as part of the Foreign Account Tax Compliance Act, and the Treasury Regulations or other official interpretations thereunder (collectively ''FATCA'').

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NSCC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NSCC has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.[3]

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Background

FATCA was enacted on March 18, 2010, as part of the Hiring Incentives to Restore Employment Act, and became effective, subject to transition rules, on January 1, 2013. The U.S. Treasury Department finalized and issued various implementing regulations (''FATCA Regulations'') on January 17, 2013. FATCA's intent is to curb tax evasion by U.S. citizens and residents through their use of offshore bank accounts. FATCA generally requires foreign financial institutions (''FFIs'') [4] to become ''participating FFIs'' by entering into agreements with the Internal Revenue Service (''IRS''). Under these agreements, FFIs are required to report to the IRS information on U.S. persons and entities that have (directly or indirectly) accounts with these FFIs. If an FFI does not enter into such an agreement with the IRS, FATCA will impose a 30% withholding tax on U.S.-source interest, dividends and other periodic amounts paid to such ''nonparticipating FFI'' (''Income Withholding''), as well as on the payment of gross proceeds arising from the sale, maturity or redemption of securities or any instrument yielding U.S.-source interest and dividends (''Gross Proceeds Withholding,'' and, together with Income Withholding, ''FATCA Withholding''). The 30% FATCA Withholding taxes will apply to payments made to a nonparticipating FFI acting in any capacity, including payments made to a nonparticipating FFI that is not the beneficial owner of the amount paid and acting only as a custodian or other intermediary with respect to such payment. To the extent that U.S.-source interest, dividend, and other periodic amount or gross proceeds payments are due to a nonparticipating FFI in any capacity, a U.S. payor, such as NSCC, transmitting such payments to the nonparticipating FFI will be liable to the IRS for any amounts of FATCA Withholding that the U.S. payor should, but does not, withhold and remit to the IRS. For the reasons described below, NSCC is not in a position to accept this liability and, by making the proposed rule changes set forth herein, is implementing preventive measures to protect itself against such liability.

In addition, under FATCA, a U.S. payor, such as NSCC, could be required to deduct Income Withholding with regard to a participating FFI if either: (x) the participating FFI makes a statutory election to shift its withholding responsibility under FATCA to the U.S. payor; or (y) the U.S. payor is required to ignore the actual recipient and treat the payment as if made instead to certain owners, principals, customers, account holders or financial counterparties of the participating FFI. NSCC is not in a position to accept this burden shift and, by making the proposed rule changes set forth herein, is implementing preventive measures to protect itself against such a burden.

As an alternative to FFIs entering into individual agreements with the IRS, the U.S. Treasury Department provided another means of complying with FATCA for FFIs which are resident in Non-U.S. jurisdictions that enter into intergovernmental agreements (''IGA'') with the United States.[5] Generally, such a jurisdiction (''FATCA Partner'') would pass laws to eliminate the conflicts of law issues that would otherwise make it difficult for FFIs in its jurisdiction to collect the information required under FATCA and transfer this information, directly or indirectly, to the United States. An FFI resident in a FATCA Partner jurisdiction would either transmit FATCA reporting to its local competent tax authority, which in turn would transmit the information to the IRS, or the FFI would be authorized/required by FATCA Partner law to enter into an FFI agreement and transmit FATCA reporting directly to the IRS. Under both IGA models, payments to such FFIs would not be subject to FATCA Withholding so long as the FFI complies with the FATCA Partner's laws mandated in the IGA.

Under the FATCA Regulations, (A) beginning January 1, 2014, NSCC will be required to do Income Withholding on any payments made to any nonparticipating FFI approved for membership by NSCC as of such date or thereafter, (B) beginning July 1, 2014, NSCC will be required to do Income Withholding on any payments made to any nonparticipating FFI approved for membership by NSCC prior to January 1, 2014 and (C) beginning January 1, 2017, NSCC will be required to do Gross Proceeds Withholding on all nonparticipating FFIs, regardless when any such FFI's membership was approved.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Commission has modified the text of the summaries prepared by the clearing agency.

[4] Non-U.S. financial institutions are referred to as ''foreign financial institutions'' or ''FFIs'' in the FATCA Regulations.

[5] As of the date of this proposed rule change filing, the United Kingdom, Mexico, Ireland, Switzerland, Spain, Norway, Denmark, Italy, and Germany have signed or initialed an IGA with the United States. The U.S. Treasury Department has announced that it is engaged in negotiations with more than 50 countries and jurisdictions regarding entering into an IGA.

Preparing for Implementation of FATCA

In preparation for FATCA's implementation, FFIs are being asked to identify their expected FATCA status as a condition of continuing to do business. Customary legal agreements in the financial services industry already contain provisions allocating the risk of any FATCA Withholding tax that will need to be collected, and requiring that, upon FATCA's effectiveness, foreign counterparties must certify (and periodically recertify) their FATCA status using the relevant tax forms that the IRS has announced it will provide.[6] Advance disclosure by an FFI client or counterparty would permit a withholding agent to readily determine whether it must, under FATCA, withhold on payments it makes to the FFI. If an FFI fails to provide appropriate compliance documentation to a withholding agent, such FFI would be presumed to be a nonparticipating FFI and the withholding agent will be obligated to withhold on certain payments.

As it applies to NSCC specifically, FATCA will require NSCC to deduct FATCA Withholding on payments to certain members and limited members arising from certain transactions processed by NSCC on behalf of such members.[7] Because FATCA treats any entity holding financial assets for the account of others as a ''financial institution,'' NSCC believes that almost all of its members and limited members which are treated as non-U.S. entities for federal income tax purposes, including those members and limited members that are U.S. branches of non-U.S. entities, will likely be FFIs under FATCA (collectively, ''FFI Members'').[8] As such, NSCC will be liable to the IRS for any failures to withhold correctly under FATCA on payments made to its FFI Members.

In light of this, NSCC has evaluated its existing systems and services to determine whether and how it may comply with its FATCA obligations. As a result of this evaluation, NSCC has determined that its existing systems cannot process the new FATCA Withholding obligations with regard to the securities transactions processed by it, as no similar withholding obligation of this magnitude has ever been imposed upon it to date, and NSCC has therefore not built its systems to support such an obligation.

In addition, the vast majority of the transactions that are processed at NSCC are processed through its Continuous Net Settlement (''CNS'') System. CNS is NSCC's core netting, allotting, and fail-control engine. Within CNS, each security and related money settlement obligation is netted to one net security and/or payment position per member, including FFI Members, with NSCC as its central counterparty. CNS maintains an orderly flow of security and money balances, providing clearance and settlement for equities, corporate bonds, unit investment trusts and municipal bonds that are eligible for book entry delivery at The Depository Trust Company (''DTC''), an affiliate of NSCC.

Further, NSCC's related Money Settlement Service provides for net money settlement with regard to payments attributable to CNS, as well as with regard to payments attributable to other Corporation-processed transactions, including mutual fund and insurance transactions. Money settlement at NSCC occurs at the end of the day and, from an operational perspective, is centralized with DTC's end-of-day money settlement in order to provide common Corporation members/DTC participants with consolidated reporting and a single point of access for all settlement information. Throughout the day, debit and credit data generated by member activity are recorded in the settlement system. At the end of the processing day, the data is summarized by product category (e.g., CNS, mutual funds, etc.) and netted to produce an aggregate debit or credit for each member. Similarly, DTC activity is also recorded and netted, separately. Following the determination of final net numbers for each Corporation member and/or DTC participant, these amounts are further netted to produce a consolidated net settlement obligation. So, for example, a member with a settlement debit at NSCC, which member is also a DTC participant, will have that debit netted against its settlement credit at DTC. Settling banks, who may settle on behalf of multiple Corporation members and/or DTC participants, must separately acknowledge the respective settlement balances of their customer members/participants at each clearing agency. The consolidated net balances of their respective member/participant customers are then further netted to produce a single net-net settling bank consolidated debit or credit. Settlement of these net-net balances occurs through use of the Federal Reserve's National Settlement Service, whereby DTC, on its own behalf and as NSCC's settlement agent, submits instructions to have the Federal Reserve accounts of the settling banks charged for their net-net debit balances and credited with their net-net credit balances. NSCC believes that this net-net settlement functionality could make FATCA Withholding virtually impossible, or, at the very least, would create onerous efficiency and liquidity issues for both NSCC and its membership.

Undertaking FATCA Withholding, given NSCC's net-net settlement functionality, could require NSCC in certain circumstances to resort to a draw on NSCC's clearing fund (''Clearing Fund'') in order to fund FATCA Withholding taxes with regard to nonparticipating FFI Members in non-FATCA Partner jurisdictions whenever the net credit owed to such FFI Member is less than the 30% FATCA tax. For example, if a nonparticipating FFI (in a non-FATCA Partner jurisdiction) is owed a $100M payment from the sale of U.S. securities, but such nonparticipating FFI is in a net debit position at the end of that day because of NSCC's net settlement functionality and end-of-day crediting and debiting, there would be no payment to this FFI Member from which NSCC can withhold. In this example, NSCC would likely need to fund the $30M FATCA Withholding tax until such time as the FFI Member can reimburse NSCC and, as NSCC has no funds for this purpose, it likely would require a draw on the Clearing Fund.[9] NSCC would need to consider an increase in the amount of cash required to be deposited into the

[6] For example, credit agreements now routinely require foreign lenders to agree to provide certifications of their FATCA status under approved IRS forms to U.S. borrowers, and subscription agreements for alternative investment funds that are anticipated to earn U.S.-source income are routinely requiring similar covenants.

[7] FFI members and limited members resident in IGA countries that are compliant with the terms of applicable IGAs should not be subject to FATCA Withholding.

[8] Currently, only a small percentage of the Corporation's members and limited members are treated as non-U.S. entities for federal income tax purposes.

[9] We note that the FATCA Regulations provide that ''clearing organizations'', which settle money on a net basis, may withhold on a similar net basis for FATCA purposes. However, the end-of-day net settlement amounts, which are attributable to the sales and dispositions of many different securities as well as debits and credits for other items, would likely not qualify for the special FATCA netting rule. Additionally, as discussed above, each of the Corporation's member's end-of-day money settlement obligation is cross-netted with such member's respective money settlement obligation at DTC, and therefore, qualifying as a ''clearing organization'' under FATCA would still not prevent the possibility that the Corporation would need to fund FATCA Withholding taxes from the Clearing Fund. Even if the end-of-day net-net settlement amount would qualify as the correct amount from which to do FATCA Withholding, the liquidity risks described herein are still present. This is because the sheer dollar value attributable to the Corporation's net daily payments among the Corporation and members means that withholding FATCA tax from such net settlement payments, in any material proportion, would likely reduce liquidity and thus increase financial instability.

Clearing Fund, either by FFI Members or perhaps all of its members, which would reduce such member's liquidity and could have significant systemic effects. The amount of the FATCA Withholding taxes would be removed from market liquidity, which could lead to increased risk of member failure and increased financial instability.

For the reasons explained above and the following additional reasons, NSCC is proposing amendments to its Rules (detailed below) to implement preventive measures that would generally require all of NSCC's (i) existing members and limited members that are treated as Non-U.S. entities for federal tax income purposes and (ii) any applicants applying to become members or limited members, that are treated as Non-U.S. entities for federal income tax purposes to be participating FFIs:

- Undertaking FATCA Withholding by NSCC (even if possible) would make it economically unfeasible for affected FFI Members to engage in transactions involving U.S. securities. It would likely also quickly cause a significant negative impact on such FFI Members' liquidity because such withholding taxes would be imposed on the very large sums that NSCC pays to such FFI Members. Furthermore, FFI Members would be burdened with extra costs and the negative impact on liquidity caused by the likely need to substantially increase the amount of cash required to be deposited into the Clearing Fund.
- The cost of implementing a FATCA Withholding system for a small number of nonparticipating FFI Members would be substantial and disproportionate to the related benefit. Under the Model I IGA form and its executed versions with various FATCA Partners, NSCC would not be required to withhold with regard to FFI residents in such FATCA Partner jurisdictions. Accordingly, NSCC's withholding obligations under FATCA would effectively be limited to nonparticipating FFI Members in non-FATCA Partner jurisdictions. Since the cost of developing and maintaining a complex FATCA Withholding system would be passed on to NSCC's members at large, it may burden members that otherwise comply with, or are not subject to, FATCA Withholding.
- As briefly noted above, if the proposed rule changes were not to take effect, in order to avoid counterparty credit risk, NSCC would likely require each of the nonparticipating FFI Members in non-FATCA Partner jurisdictions to make initial or additional cash deposits to the Clearing Fund as collateral for the approximate potential FATCA tax liability of such nonparticipating FFI Member or otherwise adjust required deposits to the Clearing Fund. The amount of such deposits, which could amount to billions of dollars, would be removed from market liquidity.
- From the nonparticipating FFI Member's perspective, having 30% of its payments withheld and sent to the IRS would have a severe negative impact on such nonparticipating FFI Member's financial status. In many cases, the gross receipts would be for client accounts, and the nonparticipating FFI Member would need to make such accounts whole. Without receipt of full payment for its dispositions, the nonparticipating FFI Member would not have sufficient assets to fund its client accounts.
- The proposed rule changes set forth herein should not create business issues or be onerous to NSCC's membership because requiring FFIs to certify (and to periodically recertify) their FATCA status, and imposing the costs of non-compliance on them, are becoming standard market practice in the United States, separate and apart from membership in NSCC.

Proposed Rule Changes

Managing the risks inherent in executing securities transactions is a key component of NSCC's business. The globalization of financial markets, the trading of more complex instruments and the application of new technology all make risk management more critical and challenging. NSCC's risk tolerances (i.e., the levels of risk NSCC is prepared to confront, under a range of possible scenarios, in carrying out its business functions) are determined by the Board of Directors, in consultation with the Group Chief Risk Officer. NSCC uses a combination of risk management tools, including strict criteria for membership, to mitigate the risks inherent in its business. In line with its risk management focus, NSCC has determined that compliance with FATCA, such that NSCC shall not be responsible for FATCA Withholding, should be a general membership requirement (A) for all applicants that are treated as non-U.S. entities for federal income tax purposes, and (B) for all existing FFI Members.[10] In connection therewith, NSCC proposes to amend its Rules as follows:

- *Rule 1:* adding ''FFI Member,'' ''FATCA,'' ''FATCA Certification,'' ''FATCA Compliance Date''[11] and ''FATCA Compliant'' as defined terms;
- *Rule 2, Section 4:* requiring that all FFI Members (both new and existing), in general: (i) Agree not to conduct any transaction or activity through NSCC if such FFI Member is not FATCA Compliant, (ii) certify and, as required under the timelines set forth under FATCA, periodically recertify, to NSCC that they are FATCA Compliant, and (iii) indemnify NSCC for any losses sustained by NSCC resulting from such FFI Member's failure to be FATCA Compliant;
- *Rule 2A, Section 1.B.:* adding FATCA Compliance as a qualification requirement for any applicant that will be an FFI Member;
- *Rule 2A, Section 1.B., Foot Note 1:* making a technical clarification to expressly include the policy statement set forth in Addendum O as other qualification standards that NSCC has promulgated with regard to certain applicants;
- *Rule 2A, Section 1.C.:* adding that each applicant must complete and deliver a FATCA Certification to NSCC as part of its membership application unless NSCC has waived this requirement with regard to membership type;
- *Rule 2B, Section 1:* Making a technical clarification by adding a footnote to expressly include the policy statement set forth in Addendum O as qualifications and standards which are continuing membership requirements;
- *Rule 2B, Section 2.B:* Specifying that failure to be FATCA Compliant creates a duty upon an FFI Member (both new and existing) to inform NSCC;
- *Addendum O:* Requiring applicants that are subject to this Policy Statement (i) to be FATCA Compliant, (ii) to deliver to NSCC a FATCA Certification, and to periodically recertify such FATCA Certification, (iii) to agree not to submit any order for processing through NSCC if the applicant fails to be FATCA Compliant at any time, and (iv) to agree to indemnify NSCC for any losses sustained by NSCC resulting from the applicant's failure to be FATCA Compliant, as conditions to admission and continued membership.
- NSCC believes the proposed rule changes are consistent with the requirements of the Exchange Act. In

[10] NSCC may grant a waiver under certain circumstances, provided, however, that NSCC will not grant a waiver if it causes NSCC to be obligated to withhold under FATCA on gross proceeds from the sale or other disposition of any property.

[11] Although Income Withholding with regard to FFI Members approved for membership by the Corporation prior to January 1, 2014 is first required under FATCA beginning July, 1 2014, the proposed amendments to the Rules would require such existing FFI Members to be FATCA compliant approximately 60 days prior to July 1, 2014 in order for the Corporation to comply with its disciplinary and notice processes as set forth in its Rules.

particular, the proposed rule changes are consistent with Section 17A(b)(3)(F) of the Exchange Act [12] because they promote the prompt and accurate clearing and settlement of securities transactions by eliminating an uncertainty in payment settlement that would arise if NSCC were subject to FATCA Withholding obligations under FATCA. The proposed rule changes are also consistent with Section 17A(b)(3)(D) of the Exchange Act [13] because they provide for the equitable allocation of reasonable dues, fees, and other charges among NSCC's members. Specifically, the proposed rule changes allow NSCC to comply with FATCA Regulations without developing and maintaining a complex FATCA Withholding system, the cost of which, as discussed above, would be would be passed on to NSCC's members at large for the benefit of a small number of nonparticipating FFI Members.

(B) Clearing Agency's Statement on Burden on Competition

NSCC does not believe that the proposed rule change will have any impact, or impose any burden, on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

NSCC has not solicited, and does not intend to solicit, comments regarding the proposed rule changes. NSCC has not received any unsolicited written comments from interested parties. To the extent NSCC receives written comments on the proposed rule changes, NSCC will forward such comments to the Commission.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

[12] 12 U.S.C. 78q–1(b)(3)(F).

[13] 12 U.S.C. 78q–1(b)(3)(D).

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 Exchange Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NSCC–2013–04 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NSCC–2013–04 This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of NSCC and on NSCC's Web site (*http://www.dtcc.com/legal/rule_filings/nscc/2013.php*). All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NSCC–2013–04 and should be submitted on or before May 29, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–10848 Filed 5–7–13; 8:45 am]

BILLING CODE 8011–01–P

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Release No. 34–69500; File No. SR–Phlx–2013–43]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Waive the Application and Initiation Fees in Certain Circumstances

May 2, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 [2] thereunder, notice is hereby given that on April 24, 2013, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's Pricing Schedule to waive the Application and Initiation Fees, for a defined period of time, in order that certain market making firms may comply with new requirements imposed by the Exchange at no additional cost.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxphlx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange recently amended various Exchange Rules to establish that member organizations may qualify to be Remote Streaming Quote Traders [3] with as many as three affiliated RSQTs.[4] RSQTs are, along with Specialists,[5] one of several types of Registered Option Traders (''ROTs'') [6] on the Exchange. SR–Phlx–2013–03 amended Rules 507 and 1014 to define a Remote Streaming Quote Trader Organization or (''RSQTO'') and a Remote Market Maker Organizations (''RMOs'').[7] In addition RSQTs may also be referred to as Remote Market Markers (''RMMs'').[8] Amended Rule 507(a) provides that ''. . . [a]s many as three RSQTs at any time may be identified by and affiliated with an RSQTO. Each of the affiliated RSQTs must be qualified as an ROT and must be in good standing.'' [9] Further, the rule change requires that ''[u]pon approval of the proposal . . . each member organization operating as an RSQT pursuant this rule will: (a) be deemed an RSQTO, and b) within 21 days notify the Exchange of no more three RSQTs affiliated with the RSQTO (the ''Conversion Period'').'' [10]

Phlx member organizations are required to have one associated person designated as their qualifying permit holder in order for the firm to be eligible for membership.[11] Further, ''[a]ny Series A–1 permit holder who is associated with a duly qualified and registered member organization (unless such holder's permit has been terminated or the rights and privileges thereof have been suspended or restricted) shall, subject to the By-Laws (including, without limitation, Section 6–1 thereof) and these Rules, be: . . . (ii) required to designate a single existing or applying member organization as such permit holder's ''primarily affiliated'' member organization for the purpose of exercising (through such member organization's designated Member Organization Representative) such permit holder's right to vote, as set forth in Article II of the By-Laws, provided that, if such holder designates any applying member organization, such holder will then also qualify such applying member organization for the purposes of Rule 921(a); and (iii) required to maintain a primary affiliation, as described in the foregoing clause (ii), with an eligible member organization at all times that such holder holds a permit.

In light of SR–Phlx–2013–03, the Exchange now requires that each RSQTO have a minimum of one affiliated RMM (an RSQT) to qualify the RSQTO. The RSQTO may have up to a maximum of three affiliated RMMS under the amended rules. The Exchange anticipates that during the Conversion Period certain RSQTOs will need to transfer their existing permit to an RMM, by filing an Individual Member Application with the Exchange for the RMM pursuant to Rule 900.2, in order to comply with the new requirements. Today, all new member applicants are assessed an Application Fee of $350.00 and an Initiation Fee of $1,500. Under the current Pricing Schedule, an RMM would be assessed these fees as a new Phlx member.

The Exchange desires to assist RSQTOs in complying with the requirements of Rule 507(a) during the Conversion Period without incurring additional costs. The Exchange, therefore, proposes to waive both the Application and Initiation Fees for existing RSQTOs desiring to file an application to transfer their existing permits to a new RMM during the Conversion Period. The Exchange will only waive the Application and Initiation Fees for RSQTOs to qualify up to one RMM, provided the existing qualifier is not an RMM today. If an RSQTO desires to qualify up to the maximum number of three RMMs, only the first application involving the transfer of the existing permit to a new RMM will receive the waiver of the Application and Initiation Fees, the other two RMMs would be assessed the Application and Initiation Fees. In addition, new RSQTOs would be assessed the Application and Initiation Fees, the waiver would only apply to existing RSQTOs.

The waiver period will be from April 24, 2013 to May 13, 2013.[12] The Exchange is proposing to add rule text to the Pricing Schedule to note the waiver period.

2. Statutory Basis

The Exchange believes that its proposal to amend its Pricing Schedule is consistent with Section 6(b) of the Act [13] in general, and furthers the objectives of Section 6(b)(4) of the Act [14] in particular, in that it is an equitable allocation of reasonable fees and other charges among Exchange members and other persons using its facilities.

The Exchange believes that the proposal is reasonable because the Exchange is seeking to lower costs for RSQTOs that are impacted by the recent amendment to Rules 507 and 1014. The Exchange does not desire to increase costs for RSQTOs attempting to comply with the new requirements of Rule 507(a) during the Conversion Period. The Exchange also believes that the proposal is equitable and not unfairly

[3] A Remote Streaming Quote Trader (''RSQT'') is defined in Exchange Rule 1014(b)(ii)(B) as an Registered Options Trader that is a member or member organization with no physical trading floor presence who has received permission from the Exchange to generate and submit option quotations electronically in options to which such RSQT has been assigned. An RSQT may only submit such quotations electronically from off the floor of the Exchange.

[4] *See* Securities Exchange Act Release No. 68689 (January 18, 2013), 78 FR 5518 (January 25, 2013) (SR–Phlx–2013–03) (a rule change which amended Phlx Rules 507 and 1014 to enable RSQT Organizations to affiliate with up to three RSQTS).

[5] A Specialist is an Exchange member who is registered as an options specialist pursuant to Rule 1020(a).

[6] A ROT includes a Streaming Quote Trader (''SQT''), a RSQT and a Non-SQT, which by definition is neither a SQT nor a RSQT. A ROT is defined in Exchange Rule 1014(b) as a regular member of the Exchange located on the trading floor who has received permission from the Exchange to trade in options for his own account. *See* Exchange Rule 1014 (b)(i) and (ii). Rule 1014 states that, in addition to other requirements, on a daily basis RSQTs and other SQTs are responsible to quote two-sided markets in not less than a specified percentage of options assigned by the Exchange at the request of such traders, unless specifically exempted from such quoting (market-making) responsibility.

[7] *See* Exchange Rule 507(a) and 1014(b)(ii)(B). *See* Securities Exchange Act Release No. 68689 (January 18, 2013), 78 FR 5518 (January 25, 2013) (SR–Phlx–2013–03). This filing became effective on April 19, 2013.

[8] *See* Rule 507(a).

[9] *Id.*

[10] *See* Rule 507(a). *See also* Options Trader Alert (''OTA'') #2013–21 dated April 22, 2013 which provided additional notice to RSQTOs of their obligation to notify the Exchange of affiliated RMMs during the Conversion Period.

[11] *See* Exchange Rule 908 entitled ''Rights and Privileges of A–1 Permits.'' Specifically, ''[a] Series A–1 permit shall only be issued to an individual who is a natural person of at least twenty-one (21) years of age. A Series A–1 permit shall only be issued to a corporation who meets the eligibility and application requirements set forth in the By-Laws and Rules, including, without limitation, Rule 972, and no individual shall hold more than a single Series A–1 permit. Series A–1 permits issued in accordance with this Rule 908 shall be in such limited or unlimited number and may be issued from time to time by the Exchange, in each case as determined by the Board of Directors in its sole discretion.'' *See* Rule 908(b).

[12] Pursuant to SR–Phlx–2013–03, the Conversion Period starts at the later of the approval of SR–Phlx–2013–03, which was on April 19, 2013, or the issuance of an OTA by the Exchange, which was on April 22, 2013, and ends 21 days later.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(4).

discriminatory because the Exchange is uniformly applying the waiver to all RSQTOs impacted by the proposal who are current members of the Exchange. All other market participants would not be affected by the rule change as it applies specifically to remote market makers. Further, new RSQTOs to the Exchange should pay Application and Initiation Fees similar to current RSQTOs that incurred those fees at the time of application.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange is waiving the fees associated with complying with Rule 507(a) during the Conversion Period for RSQTOs that would be impacted and incur fees not borne by other Exchange members. The Exchange does not believe that the waiver creates an undue burden on competition, rather the waiver attempts to equalize the treatment of its members in not imposing higher costs on market making firms.

The Exchange operates in a highly competitive market, comprised of eleven exchanges, in which market participants can easily and readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. Accordingly, the fees that are assessed are influenced by robust market forces and therefore must remain competitive with fees charged and rebates paid by other venues and therefore must continue to be reasonable and equitably allocated to those members that opt to direct orders to the Exchange rather than competing venues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[15] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–Phlx–2013–43 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2013–43. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2013–43 and should be submitted on or before May 29, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–10875 Filed 5–7–13; 8:45 am]

BILLING CODE 8011–01–P

[15] 15 U.S.C. 78s(b)(3)(A)(ii).

[16] 17 CFR 200.30–3(a)(12).

SOCIAL SECURITY ADMINISTRATION

Agency Information Collection Activities; Proposed Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB)

Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov.*

(SSA)

Social Security Administration, DCRDP, Attn: Reports Clearance Director, 107 Altmeyer Building, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov.*

The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than July 8, 2013. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. Work Incentives Planning and Assistance Program—0960–0629. As part of SSA's strategy to assist Social Security Disability Insurance (SSDI)

beneficiaries and Supplemental Security Income (SSI) recipients who wish to return to work and achieve self-sufficiency, SSA established the Work Incentives Planning and Assistance (WIPA) program. This community-based, work incentive, planning and assistance project collects identifying claimant information via project sites and community work incentives coordinators (CWIC). SSA uses this information to ensure proper management of the project, with particular emphasis on administration, budgeting, and training. In addition, project sites and CWICs collect data from SSDI beneficiaries and SSI recipients on background employment, training, benefits, and work incentives. SSA is interested in identifying SSDI beneficiary and SSI recipient outcomes under the WIPA program to determine the extent to which beneficiaries with disabilities and SSI recipients achieve their employment, financial, and health-care goals. SSA will also use the data in its analysis and future planning for SSDI and SSI programs. Respondents are SSDI beneficiaries, SSI recipients, community project sites, and employment advisors.

Type of Request: Revision of an OMB-approved information collection.

Modality of collection	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSDI and SSI Recipients	40,000	1	30	20,000
Project Sites	96	1	15	24
CWICs	400	1	20	134
Totals	40,496			20,158

2. Request to Withdraw a Hearing Request; Request to Withdraw an Appeals Council Request for Review; and Administrative Review Process for Adjudicating Initial Disability Claims—20 CFR Parts 404, 405, and 416—0960–0710. Claimants have a statutory right under the Social Security Act and current regulations to apply for SSDI benefits or SSI. SSA must collect information at each step of the administrative process to adjudicate claims fairly and efficiently. SSA collects this information to establish a claimant's right to administrative review and the severity of the claimant's alleged impairments. SSA uses the information to determine entitlement or continuing eligibility to disability insurance benefits or SSI payments and to enable appeals of these determinations. In addition, SSA collects information on Forms HA–85 and HA–86 to allow claimants to withdraw a hearing request or an Appeals Council review request. The respondents are applicants for title II disability insurance benefits or title XVI SSI.

Type of Request: Revision of an OMB-approved information collection.

20 CFR section number	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated annual burden (hours)
404.961, 416.1461, 405.330, and 405.366	12,220	1	20	4,073
404.950, 416.1450, and 405.332	1,040	1	20	347
404.949 and 416.1449	2,868	1	60	2,868
405.334	20	1	60	20
404.957, 416.1457, and 405.380	21,041	1	10	3,507
405.381	37	1	30	19
405.401	5,310	1	10	885
404.971 and 416.1471 (HA–85; HA–86)	1,606	1	10	268
404.982 and 416.1482	1,687	1	30	844
404.987 & 404.988 and 416.1487 & 416.1488 and 405.601	12,425	1	30	6,213
405.372(c)	5,310	1	10	885
405.1(b)(5) 405.372(b)	833	1	30	417
405.505	833	1	30	417
405.1(c)(2)	5,310	1	10	885
405.20	5,310	1	10	885
Totals	75,850			22,533

Dated: May 3, 2013.

Faye Lipsky,

Reports Clearance Director, Social Security Administration.

[FR Doc. 2013–10877 Filed 5–7–13; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–2012- DOT–OST–2012–0184]

Privacy Act of 1974; Department of Transportation, Office of the Secretary of Transportation; DOT/ALL–25; Department of Transportation Biographies System of Records

AGENCY: Office of the Departmental Chief Information Officer, Office of the Secretary of Transportation, DOT.

ACTION: Notice of Privacy Act system of records and consolidate two legacy systems of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Transportation's Office of the Secretary of Transportation (DOT/OST) intends to establish a DOT-wide System of Records of Transportation system of records titled, ''DOT/ALL–25, Department of Transportation Biographies System of Records.'' The Department also intends to consolidate the following legacy record systems DOT/FAA 837 Photographs and Biographical Information (April 11, 2000) and DOT/MARAD 011 Biographical Files (April 11, 2000) as part of the same. This system of records will allow the Department of Transportation, to include its Operating Administrations and Secretarial Offices, to collect and maintain biographical information of Department of Transportation employees and other individuals for the purpose of publicizing skills, experiences, and expertise relevant to Department of Transportation activities and services. These records are separate and distinct from and are not compiled from records maintained by the Department for any other function including but not limited to human resources. This system, titled Biographies, will be included in the Department of Transportation's inventory of record systems.

DATES: Written comments should be submitted on or before May 31, 2013. The Department may publish an amended SORN in light of any comments received. This new system will be effective May 31, 2013.

ADDRESSES: You may submit comments, identified by docket number DOT–2012–DOT–OST–2012–0184 by any of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. 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 Ave. SE., between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal Holidays.
- *Fax:* (202) 493–2251.

Instructions: You must include the agency name and docket number DOT–OST–2012–0184. 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, business, labor union, etc.). You may review DOT's complete Privacy Act statement in the **Federal Register** published on January 17, 2008 (73 FR 3316–3317).

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: For questions, please contact: Claire W. Barrett, Departmental Chief Privacy Officer, Privacy Office, Department of Transportation, Washington, DC 20590; *privacy@dot.gov;* or (202) 366–8134.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Transportation (DOT)/Office of the Secretary of Transportation (OST) proposes to issue a DOT system of records titled, ''DOT/ALL–25 Biographies.''

The Department wishes to create a new system of records for biographical information, including photographs, of senior leadership, employees and others who are engaged in activities on behalf of the Department. The Department will use this biographical information to provide information to the media and the public about agency expertise and services, to provide introductory materials for speeches and other events and meetings, and to provide information to the media and public about the qualifications of the Department's employees, contractors, or others about whom the Department collects biographical information. The Department also intends to consolidate the following legacy record systems DOT/FAA 837 Photographs and Biographical Information (April 11, 2000) and DOT/MARAD 011 Biographical Files (April 11, 2000) as part of the same. These records are separate and distinct from and are not compiled from records maintained by the Department for any other function including but not limited to human resources.

These routine uses are compatible with the purposes for which the information was collected. Individuals whose PII is in this system of records have provided it to DOT to enable DOT to make that information available to the public, through the DOT Web site or other means, for the purpose of furthering DOT missions and promoting its expertise.

The information contained within this system of records will be collected directly from the individual employees or individuals who are the subject of the record. Through this collection mechanism, these individuals will have the opportunity to determine which categories of their PII may be disclosed pursuant to the routine uses provided in this SORN. All collections are voluntary and individuals may request that use of the information be discontinued at any time. This updated system will be included in DOT's inventory of record systems.

II. Privacy Act

The Privacy Act (5 U.S.C. 552a) governs the means by which the Federal Government collects, maintains, and uses personally identifiable information (PII) in a System of Records. A ''System of Records'' is a group of any records under the control of a Federal agency from which information about individuals is retrieved by name or other personal identifier. The Privacy Act requires each agency to publish in the **Federal Register** a System of Records notice (SORN) identifying and describing each System of Records the agency maintains, including the purposes for which the agency uses PII in the system, the routine uses for which the agency discloses such information outside the agency, and how individuals to whom a Privacy Act record pertains can exercise their rights under the Privacy Act (e.g., to determine if the system contains information about them and to contest inaccurate information).

In accordance with 5 U.S.C. 552a(r), DOT has provided a report of this system of records to the Office of Management and Budget and to Congress.

SYSTEM OF RECORDS

Department of Transportation (DOT)/ALL—25

SYSTEM NAME:

Department of Transportation (DOT)/ALL—25, Biographies System of Records

SECURITY CLASSIFICATION:

Unclassified

SYSTEM LOCATION:

Records are maintained at the Department of Transportation and in component offices of the Department of Transportation in both Washington, DC and field offices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Any individual, including Department of Transportation senior leadership, past and present, whose biographical information is collected and distributed by DOT.

CATEGORIES OF RECORDS IN THE SYSTEM:

Categories of records in the system may include but are not limited to:

- Individual's name;
- Individual's place of birth;
- Individual's photo;
- Individual's work history and experience;
- Individual's education;
- Individual's military experience;
- Individual's civil duties and awards;
- Individual's hometown;
- Individual's other relevant areas of information that may be collected and distributed to the public.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; The Federal Records Act, 44 U.S.C. 3101; 49 U.S.C. 301

PURPOSE(S):

The purpose of this system is to collect biographical information of individuals, primarily DOT employees and senior leadership, in order to provide information to the media and the public.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DOT as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. To individuals or organizations, both public and private, for the purpose of introduction at speaking engagements, meetings and other events;

2. To professional societies, civil clubs, industrial and other organizations, Federal, state and local government agencies, representatives of the news media, researchers, authors, Congress, and members of the public by posting such information on the Internet or in DOT publications to further of DOT mission and activities;

3. To professional societies, civil clubs, industrial and other organizations, state and local governments, representatives of the news media, and other Federal, state and local government agencies for publications related to DOT's mission and activities;

4. See ''Prefatory Statement of General Routine Uses'' (available at *http://www.dot.gov/privacy/privacyactnotices*). Other possible routine uses of the information, applicable to all DOT Privacy Act systems of records, are published in the **Federal Register** at 75 FR 82132, December 29, 2010, and 77 FR 42796, July 20, 2012 (available at *http://www.dot.gov/privacy*).

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored electronically and/or on paper in secure facilities. Electronic records may be stored on magnetic disc, tape, digital media, and CD–ROM.

RETRIEVABILITY:

Records may be retrieved by individual's name.

SAFEGUARDS:

Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DOT automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RETENTION AND DISPOSAL:

DOT is preparing a new records disposition schedule (Standard Form 115) for submission to the National Archives and Records Administration (NARA), which will include the following proposed retention periods: Records at the executive level (e.g. Secretary, Deputy Secretary, and Chief of Staff) are permanent. These records are cut off when superseded or obsolete, and are transferred to NARA one year after cut off. Other records will be retained for two years from the date of collection and then disposed.

DOT will retain all records until a disposition schedule is approved by NARA.

SYSTEM MANAGER AND ADDRESS:

For office of the secretary components of DOT, the system manager is the Director, Public Affairs, Department of Transportation, 1200 New Jersey Ave. SE., Washington, DC, 20590. For Operating Administrations of DOT, the System Manager can be found at *http://www.dot.gov/briefingroom* under ''Press Offices.''

NOTIFICATION PROCEDURE:

Individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the modal Privacy Officer where the records are kept whose contact information can be found at *http://www.dot.gov/foia* under ''Contact Us.'' If an individual believes more than one component maintains Privacy Act records concerning him or her, the individual may submit the request to the Departmental Freedom of Information Act Office, U.S. Department of Transportation, Room W94–122, 1200 New Jersey Ave. SE., Washington, DC 20590, ATTN: FOIA request.

When seeking records about yourself from this system of records or any other Departmental system of records your request must conform with the Privacy Act regulations set forth in 49 CFR part 10. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Chief Freedom of Information Act Officer, *http://www.dot.gov/foia* or 202.366.4542. In addition you should provide the following:

An explanation of why you believe the Department would have information on you;

- Identify which component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created;
- Provide any other information that will help the FOIA staff determine which DOT component agency may have responsive records; and

If your request is seeking records pertaining to another living individual,

you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without this bulleted information the component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

RECORD ACCESS PROCEDURES:

See ''Notification procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification procedure'' above.

RECORD SOURCE CATEGORIES:

Records are obtained from DOT employees and other individuals who are the subject of such records. Collection and use of all records is voluntary and individuals may decline from providing such information for the purposes described within this notice.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Issued in Washington, DC on May 2, 2013.

Claire W. Barrett,

Departmental Chief Privacy Officer.

[FR Doc. 2013–10842 Filed 5–7–13; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[FHWA Docket No. FHWA–2013–0014]

Including Specific Pavement Types in Federal-aid Highway Traffic Noise Analyses

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice; request for comment.

SUMMARY: The FHWA requests input from stakeholders and interested parties on expanding the specific pavement types used in Federal-aid highway traffic noise analyses. Current highway traffic noise analyses rely on data from three pavement types: dense-graded asphaltic concrete (DGAC), open-graded asphaltic concrete (OGAC), and Portland cement concrete (PCC). Prediction of future noise levels is based on the ''average'' pavement type, calculated as the average of the DGAC and PCC vehicle noise emission levels.

The FHWA is issuing this **Federal Register** Notice to invite stakeholders and interested parties to provide comments and suggestions on whether and how to include additional pavement types in Federal-aid highway traffic noise analyses.

DATES: Comments must be received on or before July 8, 2013. Late comments will be considered to the extent practicable.

ADDRESSES: Mail or hand deliver comments to the U.S. Department of Transportation, Dockets Management Facility, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, or fax comments to (202) 493–2251. Alternatively, comments may be submitted to the Federal eRulemaking portal at *http://www.regulations.gov.* All comments must include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments electronically. Anyone is able to search the electronic form of all comments in any one of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, or labor union). Anyone may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70, Pages 19477–78).

FOR FURTHER INFORMATION CONTACT: For questions about the program discussed herein, contact Mr. Mark Ferroni, Office of Natural Environment, (202) 366–3233, or via email at *mark.ferroni@dot.gov.* For legal questions, please contact Mr. Robert Black, Office of the Chief Counsel, (202) 366–1359, or via email at *robert.black@dot.gov.* Office hours are from 8:00 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

You may submit or retrieve comments online through the Federal eRulemaking portal at: *http://www.regulations.gov.* The Web site is available 24 hours each day, 365 days each year. Please follow the instructions. Electronic submission and retrieval help and guidelines are available under the help section of the Web site. An electronic copy of this document may also be downloaded from the Office of the Federal Register's home page at: *http://www.archives.gov* and the Government Printing Office's Web page at: *http://www.access.gpo.gov/nara.*

Background

Section 109(i) of Title 23, United States Code authorizes FHWA to issue noise standards which are set forth in 23 CFR Part 772. Highway traffic noise analyses provide data for decisionmakers to make informed decisions on project alternatives and noise abatement measures. Current highway traffic noise analyses rely on data from three pavement types: DGAC, OGAC, and PCC. Prediction of future noise levels is based on the ''average'' pavement type, calculated as the average of the DGAC and PCC vehicle noise emission levels.

The FHWA remains actively involved in what the highway noise industry refers to as ''low noise pavements'' or ''quieter pavements.'' In 2003, the FHWA entered into the Quiet Pavement Pilot Program with the Arizona Department of Transportation, co-sponsored the 2004 International Scan on ''Quieter Pavement Systems in Europe,'' and funded several national workshops, trainings, and informational outreach pieces on this topic.

In 2005, the FHWA began funding the ''Pavement Effects Implementation Study'' (PEI) to look at ways to incorporate options to consider a wider range of asphaltic concrete and PCC pavements within the agency's traffic noise model. When using the term, ''specific pavement types, '' within the Federal-aid highway traffic noise analyses, the FHWA is referring to these pavements used in the PEI Study, but also any other specific pavement that a highway agency may want to consider in their noise analysis. For more information on the PEI see: *http://www.fhwa.dot.gov/environment/noise/traffic_noise_model/documents_and_references/pavement_effects_implementation_study/pei00.cfm*).

Because of the evolution of the use of quiet pavements in the highway industry, the FHWA is interested in how some of these new technologies and techniques could potentially be integrated into the FHWA's noise program to offer the most flexibility and utility to our stakeholders. The FHWA requests input from stakeholders and other interested parties on including specific pavement types in Federal-aid highway traffic noise analyses. While the FHWA invites any comments regarding use of specific pavement types in Federal-aid highway traffic noise analyses, the following questions may serve as a guide:

(1) What is your position regarding the possible inclusion of specific pavement types in the Federal-aid highway traffic noise analysis process?

(a) If you support the inclusion of specific pavement types, explain why, how you think this should be implemented (from both a regulatory

and procedural standpoint), and when this should be implemented.

(b) If you do not support the inclusion of specific pavement types, explain why (from both a regulatory and procedural standpoint), and what, if anything, the FHWA should do regarding tire-pavement noise in the highway traffic noise analysis and abatement process.

(2) Should highway agencies be required to use a more specific pavement type(s) in their future condition noise predictions?

(3) Should a State highway agency be required to maintain the specific pavement type it selected to reduce the noise impacts of a project to a level that resulted in a certain noise abatement measure?

(4) Should highway agencies be required to call a project a Type I project if the original pavement is replaced or overlaid with a louder pavement or when a pavement no longer is achieving its noise reduction?

(5) Should specific pavement types in the Federal-aid highway traffic noise analyses process be introduced as a pilot program?

(a) If you would support a pilot program, explain why, how many highway agencies should be selected to pilot this and, whether your agency would be willing to be a pilot State.

(b) If you do not support this as a pilot program, explain why you do not support this.

(6) Have you done or are you currently doing tire pavement noise research?

(a) If you have done or currently are doing tire pavement research: What is this research? Why are you doing this research? How are you or how do you plan on implementing this research? What are your goals regarding this research and/or its implementation?

(b) If you have not done or if you do not plan on doing tire pavement research, please explain why?

(7) Any additional comments?

Authority: 23 U.S.C. 101(a), 104, 109(d), 114(a), 217, 315, and 402(a); 23 CFR 1.32; and, 49 CFR 1.85.

Issued on: April 26, 2013.

Victor M. Mendez,

Administrator, Federal Highway Administration.

[FR Doc. 2013–10910 Filed 5–7–13; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket No. NHTSA–2013–0051]

Reports, Forms, and Recordkeeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Request for public comment on proposed collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections.

This document describes an Information Collection Request (ICR) for which NHTSA intends to seek OMB approval.

DATES: Comments must be submitted on or before July 8, 2013.

ADDRESSES: You may submit comments identified by DOT Docket ID Number NHTSA–2013–0051 using any of the following methods:

Electronic submissions: Go to *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

Mail: Docket Management Facility, M–30, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.

Hand Delivery: West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Fax: 1–202–493–2251.

Instructions: Each submission must include the Agency name and the Docket number for this Notice. Note that all comments received will be posted without change to *http://www.regulations.gov* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Randolph Atkins, Ph.D., Contracting Officer's Technical Representative, Office of Behavioral Safety Research (NTI–131), National Highway Traffic Safety Administration, 1200 New Jersey Ave. SE., W46–500, Washington, DC 20590. Dr. Atkins' phone number is 202–366–5597 and his email address is *randolph.atkins@dot.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulations (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following:

(i) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) How to enhance the quality, utility, and clarity of the information to be collected; and

(iv) How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks for public comment on the following proposed collection of information:

Title: Matching Countermeasures to Driver Types and Speeding Behaviors.

Type of Request: New information collection request.

OMB Clearance Number: None.

Form Number: NHTSA 1198.

Requested Expiration Date of Approval: 3 years from date of approval.

Summary of the Collection of Information: The National Highway Traffic Safety Administration (NHTSA) proposes to collect information from a stratified random sample of 3200 licensed drivers in the State of Idaho to collect information on speeding and traffic safety. The sample will be stratified by age, gender, and number of speeding citations in the previous three years (no citations, one citation, two or more citations). The survey will ask about attitudes and behaviors related to speeding and driving speeds on various types of roads, speeding countermeasures, the influence of passengers and driving environment on speed choices, and personal driving experiences. The average amount of time to complete the survey is estimated to be about 21 minutes.

The survey will be conducted as an address-based mail survey with the mailings sent out by the Idaho Transportation Department. It will include a pre-survey letter and a series of mailed reminders. Completed questionnaires will be returned in postage-paid pre-addressed envelopes to NHTSA's contractor for this project, Battelle. The survey will be administered only once per respondent. It will be made available on-line for any respondents that prefer to do the survey on-line. The on-line option is included to ensure adequate participation by younger drivers. No personally identifiable information will be collected; all results will be reported in the aggregate.

Description of the Need for the Information and Proposed Use of the Information—The National Highway Traffic Safety Administration (NHTSA) was established by the Highway Safety Act of l970 (23 U.S. C. 101) to carry out a Congressional mandate to reduce the number of deaths, injuries, and economic losses resulting from motor vehicle crashes on the Nation's highways. Speeding is one of the primary factors involved in vehicle crashes. In 2011, speeding was a contributing factor in 30% of all fatal crashes and the loss of 9,994 lives. The estimated economic cost to society for speeding-related crashes is $40.4 billion per year. Given the widespread occurrence of speeding and the high toll in injuries and lives lost in speed-related crashes, as well as the high economic costs of speed-related crashes, this is a safety issue that demands attention.

Given there has been so little progress in reducing the percentage of speeding-related fatalities over the last decade, it is appropriate to examine new approaches for addressing this problem. Recent research findings reveal important differences in driver types and speeding behaviors and provide an opportunity to develop new countermeasures and more targeted approaches to reduce speeding-related fatalities and injuries. The data collected in this study will provide NHTSA with important detailed information that will help to better define the nature of the speeding problem and assist in reducing speeding on our nation's highways. In support of its mission, NHTSA will use the findings from this survey for developing new speeding countermeasures that are better matched to specific types of speeding problems. This new information on driver types and countermeasures for speeding can help communities throughout the country to enhance and improve their speed management programs. This information is focused on achieving the greatest benefit in decreasing crashes and resulting injuries and fatalities, and providing informational support to States, localities, and law enforcement agencies that will aid them in their efforts to reduce traffic crashes.

Description of the Likely Respondents (Including Estimated Number, and Proposed Frequency of Response to the Collection of Information)—After a thorough search for a State to participate in this project, an agreement with the State of Idaho was established to conduct this study. The survey respondents will be a random sample of drivers currently licensed and living in Idaho. The sample will be stratified by age, gender, and numbers of citations for speeding in the previous three years. The questionnaire will be mailed to respondents and also made available on-line. A final sample size of 3,200 drivers is projected for the survey mailing with a projected response rate of 50% (1,600 drivers). All respondents will surveyed only once and participation in the survey is voluntary.

Estimate of the Total Annual Reporting and Recordkeeping Burden Resulting From the Collection of Information—The total estimated annual burden is approximately 560 hours for the survey. Based on cognitive testing of the paper and pencil survey (n = 9), it is estimated it will take approximately 21 minutes per respondent to complete the survey (1,600 respondents × 21 minutes each = 560 hours total). The survey would be fielded for a two-month period in 2014. The mailed survey packets would include a postage-paid return envelope for returning the completed questionnaires. Respondents will also have the option of completing the survey on-line. The mean hourly wage for all occupations in the State of Idaho is $18.52. At 560 total responding hours for the survey, this would put the cost burden at approximately $10,371.20. The respondents would receive a $5.00 incentive for taking the survey. The respondents would not incur any reporting cost from the information collection beyond the time to respond to the information request and they would not incur any record keeping burden or record keeping cost from the information collection.

Authority: 44 U.S.C. 3506(c)(2)(A).

Issued on: May 3, 2013.

Jeff Michael,

Associate Administrator, Research and Program Development.

[FR Doc. 2013–10930 Filed 5–7–13; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2013–0058]

Model Specifications for Breath Alcohol Ignition Interlock Devices (BAIIDs)

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice revises the Model Specifications for Breath Alcohol Ignition Interlock Devices (BAIIDs). The Model Specifications are guidelines for the performance and uniform testing of BAIIDs. These devices are designed to prevent a driver from starting a motor vehicle when the driver's breath alcohol concentration (BrAC) is at or above a set alcohol level. Every State in the United States has enacted a law providing for the use of BAIIDs as a sanction for drivers convicted of driving while intoxicated offenses. This notice revises the 1992 Model Specifications, to test BAIIDs for conformance. These Model Specifications are based, in part, on input from interested parties during an open comment period. This notice also indicates that NHTSA will delay rendering a decision about the feasibility and timing of a Conforming Products List (CPL) until more information is available. Accordingly, NHTSA plans to conduct an assessment to determine whether establishing and maintaining a CPL is feasible, prior to rendering a decision.

DATES: *Effective Date:* This notice is effective May 8, 2014.

FOR FURTHER INFORMATION CONTACT: *For technical issues:* Ms. De Carlo Ciccel, Behavioral Research Division, NTI–131, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; Telephone number: (202) 366–1694; Email: *decarlo.ciccel@dot.gov. For legal issues:* Ms. Jin Kim, Attorney-Advisor, Office of the Chief Counsel, NCC–113, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; Telephone number: (202) 366–1834; Email: *jin.kim@dot.gov.*

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I. Background

In 1992, the National Highway Traffic Safety Administration (NHTSA) adopted and published Model Specifications for Breath Alcohol Ignition Interlock Devices (BAIIDs). (57 FR 11772.) Ignition interlocks are alcohol breath-testing devices installed in motor vehicles that require the driver to provide an acceptable breath sample in order to start the engine. If the breath sample provided by the driver contains more than a predetermined alcohol concentration, the ignition interlock device prevents the vehicle from starting. Ignition interlocks also require drivers to provide breath samples periodically while the engine is running, to ensure that their alcohol concentration remain under the predetermined level.

Before NHTSA adopted the Model Specifications in 1992, a number of States enacted laws authorizing the use of ''certified'' BAIIDs. However, there was no single standard or test procedure among the States for certifying BAIIDs. Manufacturers of ignition interlock devices requested that the Federal Government develop and issue standards for certifying such devices rather than leaving the industry subject to numerous State standards and test requirements. After notice and comment, NHTSA adopted the Model Specifications for BAIIDs to provide a degree of consistency.

Since the Model Specifications were adopted in 1992, many States have incorporated them or some variation into their certification requirements. Persons required to use BAIIDs are generally under the direct supervision of a court or another State agency (e.g., Motor Vehicle Administration). All 50 States have enacted laws providing for the use of BAIIDs for impaired driving offenders. Currently, of these States, 18 mandate or highly incentivize the use of BAIIDs by all impaired driving offenders (including first-time offenders); an additional 20 States mandate the use of BAIIDs by repeat and/or high BAC offenders (at .15 or greater).

While many States have incorporated the Model Specifications to certify BAIIDs used by impaired driving offenders, there remains considerable variability among State certification requirements. Due to this variability and rapid technological advances in the industry, States and manufacturers of BAIIDs had requested that NHTSA update the Model Specifications. They also urged NHTSA to test the devices against the Model Specifications and maintain a Conforming Products List (CPL) of devices found to meet the Model Specifications.

A. 2006 Request for Comments

In preparation for the revision of the Model Specifications, NHTSA published two notices in the **Federal Register**. On February 15, 2006 (71 FR 8047), NHTSA published a request for comments, explaining that the agency intended to revise the 1992 Model Specifications and was interested in obtaining comments from interested parties in 13 specific areas. The areas included: Accuracy and precision requirements; sensor technology; sample size requirements; temperature extreme testing; radio frequency interference (RFI) or electromagnetic interference (EMI); circumvention testing; the vehicle-interlock interface; calibration stability; ready-to-use times; NHTSA testing; international harmonization; specifications for ignition interlock programs; and acceptance testing.

B. 2010 Proposed Model Specifications

In general, the comments to the 2006 notice were supportive of the agency's intent to revise the 1992 Model Specifications, but they noted that some adjustments were warranted to assure more consistency in the quality of equipment in use at that time. On October 6, 2010 (75 FR 61820), NHTSA published a separate notice containing proposed revisions to the 1992 Model Specifications. That notice addressed the 13 topics that had been listed in the **Federal Register** notice published in 2006. It also addressed additional issues that were raised in the comments responding to the 2006 notice, including: Set points; removable sensing heads or units; tampering testing; service interval; retests; among others.

II. Comments Received in Response to 2010 Notice

NHTSA received comments from 20 individuals and organizations in response to the 2010 notice, including five States (Iowa, Illinois, Oklahoma, Wisconsin and Colorado); nine BAIID manufacturers (Alcohol Countermeasure Systems (ACS), Alcohol Detection Systems (ADS), Consumer Safety Technology (CST), Draeger Safety Diagnostics, Guardian Interlock Systems, LifeSafer Interlock, National Interlock Systems, Omega Point Systems and Smart Start); one manufacturer of Evidential Breath Testing Devices (Intoximeters); one citizen; two coalitions/associations (American Association of Motor Vehicle Administrators (AAMVA) and the Coalition of Ignition Interlock Manufacturers (CIIM)); and two BAIID installers/providers (Ignition Interlock

Systems of Iowa (IISI) and Road Safety Technologies).

A. General Comments

Many of the comments were supportive of the proposed changes to the Model Specifications. However, a number of comments raised serious concerns. Many comments suggested that, despite NHTSA statements to the contrary, some aspects of the proposed Model Specifications seemed tantamount to program guidelines or design (and not performance) specifications. In addition, a number of comments suggested that NHTSA seemed ''out of touch'' with certain current State practices and technology, and the proposed Model Specifications seemed ''inflexible'' in some respects. These comments stressed that certain aspects of the proposed Model Specifications would negatively impact technical innovation and State programs. Other, more technical, issues were also raised.

NHTSA appreciated receiving the many candid and thoughtful comments submitted in response to the 2010 notice. The agency has considered them carefully and made a number of revisions to the Model Specifications as a result. In particular, the agency agrees that the Model Specifications should define performance criteria and not specify design features. The agency also agrees that some decisions are programmatic in nature and should not be included in these Model Specifications, which are intended to apply to the performance of BAIID units, not the manner in which States and local jurisdictions conduct their programs. The agency defers to the discretion of States and local jurisdictions regarding programmatic decisions and, as appropriate, seeks to incorporate flexibility in these Model Specifications, in an effort to support the programmatic decisions of States and local jurisdictions.

In this notice, the agency first discusses these overarching issues, which generated the greatest number of comments. Discussions about the more technical issues, which relate more directly to particular sections of the Model Specifications, follow.

Another topic that generated many comments related to the question of whether NHTSA should undertake the responsibility of evaluating ignition interlocks against the Model Specifications and publish a CPL of devices meeting those specifications. For reasons described in more detail later in this notice (Section II.E.), NHTSA will delay rendering a decision about the feasibility and timing of a CPL until more information is available. NHTSA plans to conduct an assessment to determine whether establishing and maintaining a CPL is feasible, prior to rendering a decision.

B. Overarching Issues

1. Sensor Technology

The **Federal Register** notice published in 2006 indicated that the 1992 Model Specifications did not address the type of sensor technology that should be used to satisfy the performance requirements, and asked whether the Model Specifications should limit sensor technology to alcohol-specific sensors (such as fuel cell technology based on electrochemical oxidation of alcohol) or other emerging sensor technologies, or whether NHTSA should not specify the sensor technology and rely instead on performance requirements. (71 FR 8047.)

In the 2010 **Federal Register** notice, NHTSA stated that, while alcohol-specific sensor technologies have made great advances, the proposal would not limit the sensor technology used in the BAIIDs as long as the BAIID meets the performance requirements of the Model Specifications. In that notice, the agency expressed the belief that this approach would allow a wider variety of options, including the use of emerging technologies as they become available. (75 FR 61822.)

The agency received nine comments regarding this topic. The comments were overwhelmingly opposed to the agency's proposal not to specify or restrict sensor technology.

For example, Road Safety Technologies stated, ''It is critical that the interlock device be as accurate as the technology can allow.'' (p. 1.) Similarly, LifeSafer asserted, ''As jurisdictions have embraced and expanded their use of BAIID technology, they have demanded alcohol-specific sensor technology. [Interlocks that] are not alcohol-specific . . . tarnish the reputation of the industry . . ., [which] undermines interlock efficacy and creates lasting misperceptions.'' (p. 4–5.) AAMVA expressed its belief that ''non-specific alcohol devices are prone to false positives and unwarranted lockouts, leading to a lower acceptance rate amongst drivers.'' (p. 1.) Colorado stated, ''it is unfortunate that the proposed specifications do not seize the opportunity to move all our programs towards greater success, customer convenience, acceptance and satisfaction by requiring alcohol-specific technology.'' (p. 2.)

NHTSA agrees with the comments that the Model Specifications should ensure that BAIIDs are as accurate as possible and that it is not desirable to accept devices that generate high levels of false positives. The agency is also persuaded by the comments that current technology has progressed sufficiently to expect that BAIIDs should be able to distinguish between alcohol and other chemicals or substances. Accordingly, the Model Specifications provide in Test 12 and 13 that BAIIDs should distinguish between alcohol and other specific substances, such as acetone and cigarette smoke, which are commonly found on breath. BAIIDs that are unable to distinguish these substances from alcohol will not meet the Model Specifications.

Some comments went further and urged the agency to require fuel cell technology and/or ban the use of semi-conductors. NHTSA declines to take this further step, since requiring one particular technology or prohibiting another would be equivalent to setting a design (and not a performance) standard.

2. Removable Heads and Fixed Control Boxes

In the 2010 notice, NHTSA proposed that the sensing unit should not be removable because it can more easily be damaged or mishandled, leading to frequent repairs and increased cost. Accordingly, NHTSA proposed to test only BAIIDs without removable sensing heads or units, though the agency clarified that it does not object to BAIIDs with a removable mouthpiece. (75 FR 61823.)

This aspect of the proposal generated a large number of comments in strong opposition. For example, Consumer Safety Technology (CST) stated that it found ''the provision for the prohibition of removal of the sensing head to be inexplicable and unjustified.'' (p. 1.) According to CST, ''All ignition interlocks have removable handsets. This provision would make every interlock noncompliant.'' (p. 1.) Road Safety Technologies pointed out that, ''In practice, many interlock providers now recommend to their customers that the sensing head be taken inside to keep it warm or cool in inclement weather [or] to prevent the vehicle from being stolen.'' (p. 1.)

Guardian asserted that placing a restriction on removable heads would be ''design restrictive.'' (p. 2.) Guardian continued, ''There should not be any restriction of design imposed by NHTSA. If a BAIID can meet . . . and successfully comply with the test requirements, the design of the device itself should be left to the manufacturer and the marketplace.'' (p. 2.)

A number of State comments also opposed the restriction. According to Illinois, ''Currently, [it] has seven vendors whose BAIIDs are certified by the Secretary of State, all of which use BAIIDs that have a removable sensing head . . . The Illinois Secretary of State has administered a BAIID program since 1995 and not once during the past 15 years has the Secretary received any complaints from BAIID users, installers or vendors that the BAIID has been damaged or mishandled as a result of removal of the sensing head.'' (p. 1) Objections were received also from other BAIID manufacturers, the Coalition of Ignition Interlock Manufacturers (CIIM), interlock providers, Iowa and Oklahoma. Wisconsin did not oppose the restriction, but urged NHTSA to specify that the sensing head be removable only by the service provider; not the customer.

NHTSA has reconsidered this aspect of its proposal based on the comments. The agency acknowledges that prohibiting removable sensing heads may constitute a design (and not a performance) standard and may unintentionally stifle new technologies. In addition, it could interfere with current State practices. Accordingly, the revised Model Specifications do not state a preference with regard to whether BAIIDs should have removable sensing heads. However, a provision has been added to the General Provisions and Features section of the Model Specifications (Section C), providing that if the BAIID has a removable sensing head, the vehicle should not start without use of the sensing head.

To ensure performance, BAIIDs should be tested as a unit under appropriate tests, as provided in the Model Specifications, including Tests 5 and 6, under extreme temperature conditions. If a BAIID includes removable components, such components should be tested in accordance with the manufacturer's user instructions.

NHTSA has not adopted the recommendation from Wisconsin to specify that only service providers may remove the sensing heads. We believe that such a restriction is a programmatic decision and does not relate to the performance of BAIID units.

NHTSA also proposed that BAIID memory should be located in a fixed control box. This aspect of the proposal was intended to prevent damage to the BAIID memory.

Draeger agreed with this aspect of the proposal, stating that it will ensure data integrity. However, most comments opposed this part of the proposal. For example, National Interlock stated, ''Current interlock technology stores data in the sampling head, the control box or both. Regardless of the memory storage location, the data is preserved in memory for download . . . We believe that it is not necessary for NHTSA to mandate that the memory storage be in a fixed control box.'' (p. 2.) Similar comments were received from Smart Start. Guardian added that this proposed restriction would limit ''innovation in product development and technological advancement'' (p. 5.) andinterfere with current State practices. Comments in opposition were received also from Iowa, Colorado, Ignition Interlock Systems of Iowa (IISI) and Alcohol Detection Systems (ADS). Oklahoma requested clarification of the terms ''memory'', ''fixed'' and ''control box.'' (p. 2.)

NHTSA has carefully considered these comments. The agency wishes to ensure the integrity of the data. However, the agency does not wish to specify design features or unnecessarily stifle new technologies. It also does not wish to interfere with current State practices. Accordingly, the revised Model Specifications have been revised to remove the specification that the memory be contained in a fixed control box. The interlock data logger of each BAIID should be tested, wherever it is maintained under the manufacturer's design.

3. Retests

As stated earlier, ignition interlocks test drivers for alcohol before they can start their vehicle's engine. Interlocks also retest drivers for alcohol periodically while the engine is running. In the 2010 notice, the agency stated that ''NHTSA does not intend that retests be conducted while the vehicle is moving, but rather while the engine is running with the vehicle stopped in a safe location on the side of the road.'' (75 Fed. Reg. 61824.)

Many of the comments objected to this statement. For example, LifeSafer asserted, ''All interlock vendors advise the client/user to pull off the road in a 'safe' place to take the retest. The practical reality is 99% of the 500,000–1,000,000 plus retests per day are not taken in this fashion, but rather safely delivered while the vehicle is in motion with little or minimal driver distraction.'' (p. 3–4.) Some of the comments asked NHTSA for evidence demonstrating that drivers are at increased risk when taking a retest.

Colorado asserted that, while requiring that a retest be conducted while ''stopped in a safe location . . . may appear to serve public safety, current interlock devices are designed to be so unobtrusive that they are easier to manipulate [than] a vehicle's sound system, GPS or climate control system.'' Moreover, Colorado argued that ''there are too many traffic situations that make pulling over less safe, even with an extended period within which to deliver the sample'' such as ''long mountain tunnels'' or ''other congested environments with tight lanes and limited shoulders.'' (p. 2.)

NHTSA is very concerned about distracted driving and the risks that distraction can pose for drivers and other road users. However, the agency acknowledges that it currently has little data regarding crashes involving drivers taking interlock retests. We will continue to monitor the data and respond to any new trends that are identified.

Draeger pointed out, in its comments, that the manner in which retests should be conducted ''is a requirement for the driver and is not directly related to the BAIID itself or its design and functionality.'' (p. 3.) NHTSA agrees with this assessment. Accordingly, while the agency strongly urges drivers to conduct retests when and where it is safe to do so, the Model Specifications no longer specify how retests should be conducted. This is more appropriately a function for States and local jurisdictions. The Model Specifications have been revised to remove this reference.

4. Alerts

In response to the 2006 notice, one commenter suggested that an interlock-specific tone (other than a honking horn) be used to alert outsiders to BAIID violations. In the 2010 notice, NHTSA responded that it does not believe that audible sounds or lights to alert the public to interlock violations are necessary. (75 FR 61826.) The agency did not include the suggestion in its proposal.

The comments in response to this aspect of the 2010 notice were mixed. Consumer Safety Technology (CST) agreed that ''the honking of the vehicle horn is disruptive enough to attract attention to a driver in violation of a . . . retest.'' (p. 9.) Smart Start did not take a position about the horn, but expressed its belief that ''it . . . promotes unsafe driving when lights are flashing on and off to alert the public.'' (p. 5.)

IISI requested the evidence that NHTSA relied on to reach the conclusion that audible sounds or lights are not necessary to alert the public to interlock violations. According to IISI, ''Our technicians, who collectively meet

with hundreds of IID users every day, would say that the threat of the honking horn on a failed or ignored random retest is the single greatest deterrent to the IID user's attempting to have another person pass a test so the impaired driver can sneak home undetected.'' (p. 1.)

Similarly, ACS asserted that NHTSA's position ''is contrary to 25 years of experience with alcohol interlock programs in which audible sounds and (to a lesser extent) visual indications are required by jurisdictional authorities as both a warning to others and a deterrent to the driver to ignore a retest requirement.'' (p. 22.)

As stated above with regard to retests, NHTSA is concerned about distracted driving and believes that certain types of alerts may serve as a distraction to drivers. On the other hand, the agency acknowledges that alerts may play an important role in creating deterrence for drivers in violation of a retest, and in drawing the attention of other drivers on the offending motor vehicle.

More importantly, upon reconsideration, NHTSA has reached the conclusion that decisions about the types of alerts that may be required and/or permitted are programmatic in nature, and should be at the discretion of States and local jurisdictions. Accordingly, the Model Specifications do not address the use of alerts. Such decisions may vary from State to State, and the options that vendors choose to offer ultimately will be dictated through the marketplace.

5. Emergency Override

Some comments received in response to the 2006 notice stated that an emergency override is a useful feature. In the 2010 notice, NHTSA declined to propose that BAIIDs must include this feature (i.e., the ability to start the vehicle without a breath test) in order to meet the Model Specifications. However, should a BAIID be equipped with an emergency override feature, NHTSA proposed to test the feature, but indicated that it could start the vehicle only once. The 2010 proposal provided that whenever the override feature was activated, the BAIID must indicate the need for service and record the use of the emergency override. No additional emergency overrides should be allowed during the lifetime of the BAIID installation. The agency proposed to test this feature. NHTSA also proposed that this emergency override feature have a default to prevent an override from being used when the BAIID malfunctions or fails. (75 FR 61825–26.)

The comments received in response to this portion of the proposal were varied. CST argued that ''emergency overrides should not be allowed as they essentially allow a drunk driver one free pass to drive drunk.'' (p. 5.) ACS and LifeSafer both agreed that emergency overrides should be allowed, but disagreed that an override should be permitted only once during the lifetime of the installation. ACS pointed out that not all jurisdictions permit the use of an emergency override, but of those that do, ''the restriction on use is typically once per monitoring period (service interval), rather than once per installation (program duration).'' (p. 21.) LifeSafer also disagreed that the override feature should not function when the BAIID malfunctions or fails. In fact, LifeSafer asserted, ''From a service standpoint, this is exactly when an override should be allowed.'' (p. 14.)

NHTSA believes the decision whether to permit the use of an emergency override feature is programmatic in nature and should be left to the discretion of States and local jurisdictions. Accordingly, as proposed, the Model Specifications do not address whether BAIIDs should be equipped with an emergency override feature. The Model Specifications have been modified to remove specifications related to emergency overrides and they remove the proposed override test.

6. Calibration Stability and Service Interval

In the 2006 notice, NHTSA asked, ''Is the duration of calibration stability testing sufficient? Should ignition interlocks be required to hold their calibration for a longer period of time, thereby requiring less frequent calibration checks?'' (71 FR 8048.)

In the agency's 2010 notice, in response to comments received, NHTSA explained that, ''The 1992 Model Specifications called for calibration stability for 7 days beyond the manufacturer's designated calibration stability period of 30, 45, or 60 days. For example, if the manufacturer required that the calibration of BAIIDs be checked after 60 days, the BAIID would need to hold the calibration for 67 days.'' (75 FR 61824.)

NHTSA proposed that BAIIDs ''must hold calibration for a minimum 30 days plus the 7-day lockout countdown described previously (i.e., 37 days) in order to conform to the Model Specifications.'' NHTSA explained that, ''Although some manufacturers have BAIIDs that are claimed to hold calibration for a longer time period, NHTSA proposes to test the calibration stability at 37 days (i.e., 30 days plus the 7-day lockout countdown) . . .'' (75 FR 61824.)

NHTSA also proposed in the 2010 notice to add service interval requirements of ''not greater than 30 days, plus a 7-day lockout countdown.'' (75 FR 61824.)

More than half of the comments addressed this issue. All of the comments objected to this aspect of the agency's proposal. Iowa described it as ''a step backwards'' (p. 1); Wisconsin said it is ''overly restrictive'' (p. 2); CST called it ''an inexplicable regression in standards that will result in increased costs to the participant and consequently result in a marked reduction in participation in state interlock programs.'' (p. 3.)

CIIM explained that ''This is an area where technology has significantly improved since the last time NHTSA asked for comments. Most devices can go 2 or 3 months without needing to have its calibration checked.'' (p. 2.) Accordingly, CIIM suggested a longer calibration period. ACS sought to clarify that calibration stability and service intervals are not the same. ''Calibration stability is a performance criterion of the BAIID to be included in Model Specifications; whereas, service interval is programmable as a function of the performance of a participant and is a program matter.'' (p. 13.) In addition, National Interlock pointed out that, ''The proposed [Model Specifications] would appear to prohibit specialized programming of the BAIID device or software to meet the specific requirements of jurisdictions.'' (p. 2.)

NHTSA agrees with the comments that current technology now permits ignition interlocks to maintain stable calibration for longer periods of time. The Model Specifications continue to provide for a *minimum* calibration stability period of 37 days (30 days plus the 7-day lockout countdown) and for BAIIDs to be tested (under Test 3) to determine conformance with this period. This minimum calibration period should provide some consistency and the 30-day period would allow results of this test to be available quickly. In addition, in recognition of recent technological advances and current practice in the field, the Model Specifications provide manufacturers with the opportunity to demonstrate that their BAIIDs can maintain their calibration stability for longer periods of time, by providing for testing of BAIIDs also at 60 days, 90 days and 180 days, plus 7 days.

As suggested in the comments, NHTSA agrees that it is appropriate to decouple the period of calibration stability and the service interval. States and local jurisdictions make decisions about service intervals based on a

number of different factors, including the need to supervise some offenders more closely or the desirability of providing an incentive (and permitting a longer service interval) for offenders who have demonstrated compliance with their sentence. In addition, NHTSA recognizes that BAIIDs can be programmed to vary the service interval, based on the circumstances in each case. Accordingly, the Model Specifications do not provide for a specific service interval period. Rather, the agency defers to States and local jurisdictions to determine the service intervals they believe are appropriate.

However, in one important respect, these two periods are very much related. States and local jurisdictions are reminded that, if they choose to use service intervals that are longer than 37 days, the BAIIDs they select should be capable of maintaining a stable calibration for the requisite period of time.

Smart Start suggested that a maximum number of violation points should be defined and allowed, and recommended 5. (p. 4.) NHTSA believes that, like the service interval, this is a programmatic issue and should be set by States and local jurisdictions. Accordingly, the Model Specifications have not been modified to specify a maximum number of violation points.

C. Technical Issues Relating to Particular Sections of the Model Specifications

1. Terms Used in Model Specifications (Section B)

The 2010 notice contained proposed definitions for 14 terms. ACS took issue with the proposed definition for the term, ''Service interval'', which the notice proposed to define as ''The maximum time period that a BAIID may be used without maintenance or data download, after which the ignition must lock.'' ACS pointed out that, ''Service interval is not a device performance criteria; it is a program guideline, which is the time period during which the participant may drive between monitoring appointments, based upon the jurisdiction restrictions and the compliance of the participant with program conditions.'' (p. 26.) NHTSA agrees with this point and has changed the definition of this term accordingly.

Oklahoma suggested that the word ''pertinent'' should be removed from the proposed definition of ''Interlock Data Logger—A device within a BAIID that records all pertinent events, dates and times during the period of installation and use of a BAIID.'' NHTSA has made this modification, as well, to avoid limiting the information that is recorded on the interlock data logger.

Other comments supported the proposed definitions.

2. General Provisions and Features of BAIIDs (Section C)

The 2010 notice proposed that BAIIDs must meet certain requirements in order to conform to the Model Specifications, including:

- Pass conformance tests 1 through 16
- Not compromise normal functions of the vehicle
- Not have a removable sensing head
- Contain memory in a fixed control box
- Have tamper proof seals
- Capable of locking out a specified BrAC at a set point of .02 g/dL with a minimum flow rate of 0.1 L/sec
- Bypass or disable a remote start device, if installed on a vehicle
- Clear instructions to the driver
- An interlock data logger that will record all start attempts and outcomes
- Track all changes to the metrological software

In addition, the notice proposed that manufacturers of BAIIDs must submit:

- The operator's manual and other documentation
- The quality assurance plan (QAP)
- A self-certification that the manufacturer meets the requirements of the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration (FDA) Good Manufacturing Practices regulations for devices used for medical purposes (21 CFR Part 820) and that the device's label meets the requirements contained in FDA's Labeling regulations for devices used for medical purposes (21 CFR 809.10).

As discussed in detail previously, the agency received many comments concerning the removable sensing head and the fixed control box, and modifications have been made to the Model Specifications in response to these comments.

The comments concurred with most of the other requirements and features. However, comments were raised regarding some of these provisions.

a. Ignition, Ignition Switch and Locking—Oklahoma (p. 1) and ACS (e.g., p. 28–30) pointed out that the 2010 notice included some incorrect references to ''ignition'', ''ignition switch'' and ''locking'' of the ignition. These references have been corrected.

b. Set point of 0.02 g/dL and minimum flow rate of 0.1 L/sec—In the 2006 notice, NHTSA asked whether the current set point of 0.025 grams of alcohol per 210 Liters of air (g/dL) is appropriate or whether it should be changed. (71 FR 8047.) The comments received in response to the 2006 notice were varied, including that the 0.025 g/dL level should not be changed, that the set point should be more stringent and that the agency should establish a set point of 0.025 g/dL for adults and 0.02 g/dL for minors.

In response to these comments, in the 2010 notice, NHTSA proposed lowering the set point from 0.025 g/dL to 0.02 g/dL. (75 Fed. Reg. 61822.) Comments received in response to this aspect of the 2010 proposal were mixed again. For example, AAMVA questioned the need to lower the set point and suggested that a lower level could lead to unwarranted lockouts. (p. 2.) IISI asked whether this change was being proposed for the purpose of enforcing ''abstinence from alcohol consumption'' as opposed to ensuring ''highway safety.'' (p. 3.) Some comments, including those from Smart Start and Wisconsin, expressed support for the proposed change. LifeSafer supported the change and suggested that BAIIDs should be required to provide and record a ''warn'' when they register at 0.01 g/dL and above. (p. 5.)

The 2010 notice proposed a minimum flow rate of 0.1 Liters per second (L/sec). (75 FR 61823.) ACS suggested it should be set no lower than 0.2 L/sec. (p. 9.)

The agency is not attempting to influence program purposes, but rather is seeking simply to define the Model Specifications to test the precision and accuracy of BAIID devices. We recognize that State BrAC levels are not uniform. Most are set at 0.02 g/dL, but others are set at other (generally higher) levels. NHTSA continues to believe that 0.02 g/dL is an appropriate set point to use for the testing of BAIIDs under these Model Specifications. This set point will ensure accuracy for the States, whether they are using 0.02 g/dL or a higher level. That choice is still each State's to make.

In addition, the change from 0.25 g/dL to 0.20 g/dL will align the BAIID Model Specifications with NHTSA's other Model Specifications, which pertain to evidential breath testing instruments (EBTs), calibrating units and alcohol screening devices. Moreover, NHTSA continues to believe that the technology is available for BAIIDs to achieve and maintain a set point at this level. Accordingly, this portion of the proposed revision is adopted without change. The recommendation to require a ''warning'' at the 0.01 g/dL level has not been adopted, since practices vary from State to State.

NHTSA agrees with ACS's comment regarding the flow rate. In fact, the 0.1

minimum flow rate included in the General Conditions and Features section of the notice was an unintentional error on the agency's part. The General Test Conditions section of the 2010 notice stated that unless specified otherwise in a particular conformance test, each test would use an ambient flow rate of 0.3 L/sec. Consistent with this provision, the General Conditions and Features section should have indicated that BAIIDs be tested with a flow rate of 0.3 L/sec. The Model Specifications have been modified accordingly.

In accordance with the revised Model Specifications, BAIIDs should record and maintain a record of all breath samples provided.

c. Federal Drug Administration (FDA) Requirements—In the 2010 notice, in response to comments received regarding the 2006 notice, NHTSA proposed that manufacturers must submit a self-certification that the manufacturer meets the requirements of the FDA Good Manufacturing Practices (GMP) regulations for devices used for medical purposes (21 CFR Part 820) and that the device's label meets the requirements contained in FDA's Labeling regulations for devices used for medical purposes (21 CFR 809.10).

Some comments supported this aspect of the proposal. CST said that holding interlock providers to this ''more rigorous'' standard was ''positive.'' (p. 3.) ACS agreed, in principle, with requiring that interlock manufacturers comply with FDA's GMP requirements, but asked how the requirement will be enforced? ACS did not believe a self-certification process would be adequate. (p. 24.)

However, most comments strongly objected to these requirements. The comments from National Interlock were representative. They stated, ''The BAIID is not a medical device and is not intended to be used for medical purposes. The application of these regulations will place tremendous cost and burden on the manufacturers of BAIIDs, with the possibility of raising costs of programs beyond what is reasonable for a driver to pay. This could result in a higher incidence of individuals driving without a license, and without a BAIID, which would be contrary to federal and state policy to increase the use of BAIIDs as an alcohol countermeasure.'' (p. 2.) Draeger added, ''Breath alcohol test systems intended solely for forensic (law enforcement) purposes are currently exempt from . . . premarket notification and other FDA requirements. . . . BAIID devices intended for use by law enforcement are therefore exempted by the FDA from GMP compliance. . . . We recommend that NHTSA defer to the FDA's judgment and guidance on this matter. . . .'' (p. 4.)

It is NHTSA's understanding that the FDA Good Manufacturing Practices (GMP) regulations (21 CFR Part 820) apply to devices used for medical purposes. While the FDA has applied these regulations to some alcohol devices, such as screeners that are used for medical purposes, the FDA has not exercised jurisdiction over instruments used for other purposes, such as Evidential Breath Testing Instruments (EBTs), which are used for law enforcement purposes. Similarly, it is our understanding that, to date, the FDA has not exercised jurisdiction over BAIIDs. In addition, NHTSA has not, at this time, reached a decision about whether it will develop a CPL. Accordingly, manufacturers of BAIIDs must comply with any applicable FDA requirements, but NHTSA has removed the reference in the Model Specifications to submission of a self-certification of compliance with the FDA regulations.

Smart Start (p. 6) and Guardian (p. 5) suggested that, if quality assurance requirements are to be imposed, NHTSA should consider using ISO standards instead of the FDA requirements. While manufacturers may adopt the ISO standards if they wish to do so, the agency does not believe there is sufficient justification to add this as a condition in the Model Specification for all manufacturers of BAIIDs.

3. BAIID Test Procedures (Section D)

The 2010 notice proposed to include 17 separate tests in the Model Specifications. It also proposed a number of general test conditions, pertaining to the number of trials, ambient temperature, ambient atmospheric pressure, sample parameters and simulated breath samples. In addition, the notice proposed a number of performance requirements relating to tests at 0.000 g/dL, 0.008 g/dL and 0.032 g/dL. The notice also proposed that a BAIID must be ready for use one minute after it is turned on and it must be ready for a second test within one minute of a preceding test.

a. General Test Conditions and Performance Requirements

The 2010 notice proposed that unless specified otherwise under a particular conformance test, BAIIDs must meet a number of performance conditions under all tests conducted.

i. Breath Sample Volume and Flow Rate

In the 2006 notice, NHTSA indicated that the 1992 Model Specifications set the minimum breath sampling size at 1.5 liters and asked whether NHTSA should consider lowering the minimum breath sampling size requirement. (71 FR 8047–48.) Most comments received in response to that notice advocated lowering the minimum sampling size to either 1.2 L or 1.0 L. In the 2010 notice, in response to these comments, NHTSA proposed lowering the minimum sampling size from 1.5 L to 1.2 L. Unless specified otherwise in the particular conformance test, BAIIDs should be tested at a volume of 1.2 liters and an ambient flow rate of 0.3L/sec. (75 FR 61822, 61828.) Breath sample volume relates to how much a person blows into a BAIID. Flow rate is the intensity of the blow.

The comments received in response to the 2010 notice were mixed. CST questioned the wisdom of lowering the minimum breath sampling size to 1.2 L, claiming that it could reduce the quality of the breath sample. (p. 3.) Wisconsin expressed a preference for retaining the size at 1.5 L (p. 2), as did Draeger, with allowances for reductions to 1.2 L upon medical recommendation (p. 4). On the other hand, Smart Start, ACS and LifeSafer all supported the reduction. Smart Start expressed the belief that this change would permit more individuals to participate in interlock programs. (p. 2.) ACS recommended that minimum back pressure also be included. (p. 8.)

NHTSA agrees that lowering the minimum breath sampling size will make the BAIID available to a larger population of users, including individuals with smaller or diminished lung capacity. No evidence was submitted to indicate that the reduced volume will diminish the integrity of breath samples. Accordingly, this element of the Model Specifications is adopted without change. If a State wishes to set its minimum breath sampling size at 1.5 L and permit a 1.2 L level upon a medical recommendation, the Model Specifications will be able to support them in that decision. The ambient flow rate will remain at 0.3 L/sec. The agency believes that the other criteria included in the Model Specifications, provide sufficient safeguards against circumvention, without the need to address back pressure as well. Accordingly, a back pressure test has not been added.

ii. Precision

The 2010 notice stated that BAIIDs must experience no ignition locks in 20

trials at 0.000 g/dL (grams of alcohol/210 liters of air); not more than one ignition lock in 20 trials at 0.008 g/dL; and not more than one ignition unlock in 20 trials at 0.032 g/dL. (75 Fed. Reg. 61828.) These performance requirements represented an increase from 90 percent to 95 percent compliance at the 0.008 and 0.032 levels and 100 percent at 0.000.

Oklahoma suggested that no ignition ''locks'' should be permitted in 20 trials at both the 0.000 and 0.008 levels and no ignition ''unlocks'' should be permitted in 20 trials at the 0.032 level. (p. 3.) Wisconsin also recommended 100% conformance at all levels. (p. 2.) Smart Start asserted that the difference between 100% and 95% ''does not matter.'' Some changes in accuracy and precision ''potentially [add] costs to the BAIID and [have] no real world added benefit.'' (p. 1.) No other comments addressed this issue. In these revised Model Specifications, NHTSA has sought to strike a balance between the capabilities of the latest technology, the variability among various products currently on the market, as well as costs and other factors. Accordingly, as proposed in the 2010 notice, the performance requirements have been increased in these revised Model Specifications at the 0.000 level, by providing that the vehicle must not be prevented from starting even once during 20 trials. However, the Model Specifications do not require 100 percent compliance at all levels. They provide that the vehicle must not be prevented from starting more than once during 20 trials at the 0.008 level and must not start more than once during 20 trials at the 0.032 level. (See Section D of the Model Specifications, Performance Requirements.)

iii. Terminology

ACS and Oklahoma noted that the terms ''locked'' and ''unlocked'', while easily understood, are technically inaccurate. They suggest that they be replaced. The agency has made adjustments in these revised Model Specifications to avoid use of these terms, such as by describing whether or not the vehicle will start, instead of using the terms ''locked'' and ''unlocked''.

iv. Readiness

The 1992 model specifications provided for a wait time of up to 5 minutes for a driver to take a breath test. A common complaint by users of BAIIDs was the long wait times for breath tests by BAIID users. Comments to the 2006 notice indicated that, with improved technology, faster ready-to-use times were achievable, even in extreme low temperatures because BAIIDs now have quick start capabilities.

The 2010 notice proposed that, unless specified otherwise in a particular test, BAIIDs must be ready for use within one minute after they are turned on and ready for a second test within one minute of a preceding test. (75 Fed. Reg. 61824.) A number of comments expressed concern that the proposed change was too extreme. ACS pointed out that, if the BrAC is at or above the set point, the BAIID will enter into a lock out period of 3–5 minutes. ACS stated, ''The examiner must request special parameter settings if a one minute retest period is required.'' (p. 29.) LifeSafer made a similar comment, suggesting that 90 seconds should be allowed ''to completely purge the prior alcohol-laden sample.'' (p. 15.) NHTSA has decided to adopt a compromise readiness time period of 3 minutes as the performance level in the Model Specifications, which the agency believes is appropriate and achievable, based on current practices and the current state of technology. NHTSA has revised the Performance Requirements in Section D of the Model Specifications to provide for this change.

No other comments were received objecting to the General Test Conditions or Performance Requirements.

b. Conformance Tests

The 2010 notice proposed 17 separate conformance tests regarding the performance of BAIIDs. Some of the tests were supported by the comments. Questions, objections and suggestions were raised regarding others. Each test, the comments that it generated and the agency's responses are discussed in detail below.

Test 1—Precision and Accuracy

As explained in the 2010 notice, ''accuracy'' is the degree to which a BAIID measures the BrAC correctly. For example, for a BAIID to be accurate, a breath sample with no alcohol present (0.000 g/dL) must not prevent the vehicle from starting. ''Precision'' is the degree to which that same measure can be repeated. In the previous example, for the BAIID to be precise, that same alcohol free breath sample should not prevent the vehicle from starting consistently over time. (75 FR 61822.)

In the 2010 notice, NHTSA proposed testing BAIIDs at ±0.012 g/dL above and below the set point of 0.02 g/dL, i.e., at 0.032 g/dL and 0.008 g/dL. (75 Fed. Reg. 61822.) Wisconsin suggested that testing should be carried out at ±25 percent so that tests would be conducted at 0.015 g/dL rather than 0.008 g/dL and 0.025 g/dL rather than .032 g/dL. (p. 2.) All other comments either supported or did not object to the proposed levels. As explained in the 2010 notice, NHTSA arrived at these proposed levels by using standard statistical techniques for small samples. (75 Fed. Reg. 61822.) The ±0.012 interval corresponds to a 2 sigma requirement for compliance. The levels proposed in the 2010 notice are adopted without change.

ACS suggested that the BAIID should record the measured BrAC value from the data log to conduct statistical analysis. (p. 29.) Draeger proposed adding a result requirement to each test point. (p. 4.) The Model Specifications do not require a numerical readout. They require only that the BAIID functions properly at each appropriate BrAC, by preventing or permitting a vehicle to start, as appropriate. BAIID manufacturers may offer a feature that provides a numerical readout, if they choose to do so. However, the Model Specifications do not specify that such a feature be offered and do not specify a test for that particular function.

Test 2—Breath Sample Volume and Flow Rate

As described above, the General Test Conditions provide that, unless specified otherwise in a particular conformance test, all tests will be conducted using a volume of 1.2 liters and a flow rate of 0.3 L/sec. The purpose of Test 2 is to evaluate the performance of BAIIDs under different breath sample volumes and flow rates. Tests 2a and 2b are designed to test the amount (volume) of air blown into the BAIID, using a smaller and a larger sample volume (1.0 and 1.5 liters, respectively). Tests 2c and 2d are designed to test the intensity (flow rate) of the blow, using a slower and a faster flow rate (0.1 and 0.7 L/sec, respectively).

The 2010 notice proposed that BAIIDs should prevent a vehicle from starting when the sample volume is 1.0 liters and permit the vehicle to start with a sample volume of 1.5 liters. (75 FR 61828.) These elements of Tests 2a and 2b are adopted without change.

The 2010 notice proposed that BAIIDs should permit the vehicle to start using both flow rates. (75 FR 61828.) As mentioned earlier in this notice in Section II.C.2.b., ACS commented that the flow rate should be set no lower than 0.2 L/sec (p. 9), and the agency agrees. Consistent with this change, the Model Specifications are revised to provide that BAIIDs should prevent a vehicle from starting when the flow rate is 0.1 L/sec and it should permit the

vehicle to start with a flow rate of 0.7 L/sec.

Test 3—Calibration Stability

These issues are discussed fully in Section II.B.6. above. In response to comments received, the Model Specifications continue to provide for a minimum calibration stability period of 37 days (30 days plus the 7-day lockout countdown) and BAIIDs should be tested (under Test 3) to determine conformance with this period. In addition, the Model Specifications provide manufacturers with the opportunity to demonstrate that their BAIIDs can maintain their calibration stability for longer periods of time, by providing for testing of BAIIDs also at 60 days, 90 days and 180 days, plus 7 days.

Test 4—Input Power

No comments were received regarding this proposed test. It is adopted without change.

Tests 5 and 6—Extreme Temperature and Humidity and Warm Up Time at −40 °C

The 1992 Model Specifications called for testing at −40 °C, −20 °C, +70 °C and +85 °C, but allowed for the removability of the alcohol sensing unit so that it may be kept at an artificial temperature when the vehicle may be subject to extremely cold or hot temperatures. In its 2006 notice, NHTSA asked whether this approach to extreme temperature testing seemed sufficient or whether it should be more stringent. (71 Fed. Reg. 8048.)

The agency received a variety of comments in response to the 2006 notice and, in 2010, proposed to retain the current extreme temperature tests at −40 °C and +85 °C, believing it to be reasonably representative of the environments encountered in the United States. In addition, NHTSA proposed to conduct additional high temperature tests for components of the BAIID installed in the passenger compartment (at +49 °C) and in the engine compartment (at +85 °C), and to specify the humidity level for these high temperature tests. The agency proposed to discontinue the tests at −20 °C and +70 °C, because the agency's experience indicated that testing at the extreme temperatures is sufficient. (75 FR 61823.)

NHTSA also proposed a warm up test in the 2010 notice to ensure that BAIIDs are ready to test and ready for retest within 3 minutes under extreme temperature conditions, at −40 °C. (75 FR 61824.)

Draeger suggested that a warm-up time of up to 3 minutes at 9V and −40 °C is overly severe, and proposed that the test be changed to require a warm-up time of up to 3 minutes at 9V and −20 °C, but most comments supported the range that NHTSA proposed in the notice. (p. 5.)

Wisconsin applauded NHTSA's proposed adoption of tests at extreme temperatures, stating that ''this will more effectively simulate BAIID operation in cold-weather climates. (p. 2.) ACS agreed that the proposed extreme temperature testing at −40 °C and +85 °C should adequately address the needs of the environmental tests for the U.S. ACS disagreed that the −20 °C and +70 °C tests should be discontinued, asserting that these temperatures provide different stress levels on devices and that Tests 5 and 6 should be conducted under all of these conditions, and at +22 °C, as well. (p. 9, 31.) Smart Start also suggested that the intermediate temperature tests should be retained. (p. 2.) LifeSafer urged the agency to harmonize the extreme temperature tests with the CENELEC (the European standard), at least on the high-side. (p. 7–8.)

NHTSA notes that the purpose of Tests 5 and 6 is to determine the BAIIDs' ability to perform at extreme temperatures and humidity. The temperatures that NHTSA included in the proposed Model Specifications are adopted without change, since they accurately represent extreme temperatures experienced in the United States. Other tests contained in the Model Specifications, including Tests 1–4 and others, should be performed at ambient temperatures. Accordingly, the agency believes intermediate temperatures need not be included under Tests 5 and 6.

Wisconsin recommended that the procedures used when testing at extreme temperatures must ensure that measurements are taken when the device is at the prescribed temperature and humidity and has not been allowed to vary. (p. 3.) NHTSA agrees with this comment. Steps should be taken during testing to prevent temperature and humidity drift, such as by testing BAIID devices in a temperature chamber.

A number of comments objected specifically to the proposed requirements regarding readiness for retest at various temperatures. ACS asserted that the requirements are overly simplistic, requiring that BAIIDs are ready for retest within three minutes at −40 °C, and one minute at −39 °C. (p. 15.) Smart Start recommended that NHTSA consider adopting the CENELEC standard regarding this requirement, which provides that devices are to be tested at an ambient temperature of −40 °C and +85 °C with no time limit; at −20 °C within 3 minutes and at −5 °C within 90 seconds. (p. 4.)

Similarly, LifeSafer sought clarification regarding the readiness requirements for this test and others, noting that the various tests seem to require that devices need to be ready for retest within one minute, three minutes, five minutes or other periods of time. According to LifeSafer, retest sequences are typically 5–6 minutes before a Refused Violation is recorded. Imposing a 90 second wait between tests will allow a user three attempts to pass the retest. LifeSafer suggested that after a fail, a 90 second (versus a 60 second) interval between test attempts will produce a more precise result and is a reasonable period to require the user to wait after failing a test. (p. 11–12.)

NHTSA acknowledges that the variety of different wait times contained in the Model Specifications could cause confusion and has decided they are not warranted. Upon further review, the agency finds that it is preferable to establish more consistency in the readiness requirements and believes the objectives of each test can be achieved with a wait time of 3 minutes. Accordingly, NHTSA has revised the Model Specifications to provide that BAIIDs must be ready for all tests and retests within a period of 3 minutes. This change represents an improvement over the 1992 Model Specifications, is not as restrictive as the 2010 proposal and is consistent with (though not identical to) the European standard. See also the discussion above in Section II.C.3.a. of this notice.

Some comments addressed the voltage levels. Lifesafer, for example, expressed concern that the 9v level would be too low at −40 °C. (p. 15.) On the other hand, ACS agreed with the agency's proposal, stating that ''this emulates a real world circumstance in a vehicle during winter months and with less than optimal batteries.'' (p. 10.) This was the agency's intention. NHTSA wanted to simulate less than optimal conditions, which commonly occur in winter. This aspect of the proposal is adopted without change.

Comments were received also concerning NHTSA's statements in the proposal prohibiting use of a removable sensing head. These comments are discussed in detail in Section II.B.2. above. As explained above, the revised Model Specifications do not prohibit the use of removable heads and provide allowances for these components under

extreme temperatures, consistent with manufacturer instructions to users.

Test 7—Vibration

The agency received no objections to the proposed vibration test, although ACS noted that, ''Instead of interpreting the requirements of the vibration test,'' NHTSA could consider simply referring to ''SAE standards for automobile electronic components.'' (p. 32.) This proposed test is adopted without change.

Test 8—Retest

Under Test 8, NHTSA proposed a series of tests to simulate the BAIID functions that must operate in connection with retests once the vehicle has been started, including an indication to the driver that a retest must be taken, and an indication that a service call is required when tested with a BrAC of 0.032.

In the 2010 notice, the agency stated that it ''does not intend that retests be conducted while the vehicle is moving, but rather while the engine is running with the vehicle stopped in a safe location on the side of the road.'' (75 FR 61824.) This issue is discussed fully in Section II.B.3. above. In response to comments received, the preamble to this notice no longer specifies how retests should be conducted. The Model Specifications also are revised to remove this reference. They otherwise are not changed.

Test 9—Tampering and Circumvention

In the 2006 notice, NHTSA stated that the 1992 Model Specifications offer a number of procedures for evaluating whether existing devices can be easily circumvented and it asked whether these procedures are sufficient or whether new or modified procedures should be added. (71 FR 8048.)

The comments to this notice criticized the Model Specifications for being confusing and lacking specificity. The comments offered a variety of specific suggestions. In the 2010 notice, NHTSA acknowledged that the circumvention requirements in the Model Specifications were confusing and proposed to clarify them and specify that BAIIDs must have tamper proof seals to indicate when a BAIID has been disconnected from the ignition. (75 FR 61823.) The 2010 proposal also included tests for ''hot wiring'', push start, un-warmed air sample, warmed air sample, cooled 0.032 BrAC sample and filtered 0.032 BrAC sample. The proposal indicated that each attempt must be noted on the interlock data logger. (75 FR 61829.) A sample format for downloaded data from an interlock data logger was included in Appendix D to the 2010 notice. (75 FR 61832–33.)

Smart Start supported the proposed tests, and emphasized the importance of anti-circumvention and anti-tampering techniques, stating, ''There is a general mistrust in public perception that anyone can test on an interlock, thereby allowing the non sober driver to start their interlock equipped vehicle. NHTSA should take the lead in setting standards that negate this negative perception and instill public confidence in this technology that can separate drinking from driving.'' (p. 3.)

However, Smart Start also suggested that the Model Specifications could go further. Other comments strongly agreed. Wisconsin stated, ''Inclusion of tamper proof seals and routine monitoring for tampering during BAIID service does not go far enough to ensure that ignition interlock devices have sufficient features to prevent circumvention and the subsequent driving by impaired individuals. The proposed model specifications should require anti-circumvention measures in addition to electronically logging these events. These measures could include use of breath signature, humidity, differing blow patterns, photography, pressure, temperature or time to prevent BAIID circumvention.'' (p. 4.)

The comments seem to support tests (a) and (b) (hot wiring and push start), but they criticized the other four tests. CST explained that these four tests ''are based upon circumventions that plagued interlock programs in the early years of [such programs]. To even conduct these tests you would need an interlock with a very rare setting, the setting that allows the breath sample to be given in a long continuous blow.'' (p. 4.)

Intoximeters asserted that tests (c)–(f) are intended to test the instruments' ability to prevent tampering and circumvention, ''but in fact do not do so.'' According to Intoximeters, ''Many BAIID devices are using a hum and blow or blow and hum method to determine if a person is providing the sample.'' (p. 1.) LifeSafer mentioned also other techniques, including the flow and suck back. (p. 9.) Intoximeters asserted, ''It is disingenuous to show that an instrument is meeting these tests, when in fact the common anti-circumvention techniques are not being tested at all.'' (p. 1.) CST indicated that thirty eight states are already using these anti-circumvention breath sample patterns. (p. 4–5.) Intoximeter suggested that these anti-circumvention methods should be reviewed and tests should be established to determine if they can be beaten. (p. 1.)

Regarding Test 9b (push start), Draeger asserted that depending on the chosen technology, it may take up to 2 minutes until the movement or motor run is detected. Accordingly, Draeger suggested that the Model Specifications should be revised to provide that the vehicle be driven for at least two minutes. (p. 5.)

NHTSA has decided to continue to include the hot wiring and push start tests (9a and 9b) in the Model Specifications. To ensure that the results are properly recorded under the push start test, the Model Specifications specify that the vehicle should be run under this test for at least two minutes.

NHTSA recognizes that increasingly, interlock companies are introducing new, more sophisticated anti-circumvention features into their products, designed to ensure that the driver is blowing into the BAIID and to prevent circumvention. Manufacturers are employing a variety of anti-circumvention methods, including blow and hum, hum and blow, and suck and blow patterns, as well as the use of cameras. NHTSA appreciates that these methods might make some of the tests proposed in the 2010 notice (9c–f) appear to be unnecessary or obsolete.

However, the revised Model Specifications do not specify the use of any particular type of anti-circumvention feature, since that would be tantamount to a design, rather than a performance, standard. In addition, since the technology associated with these features is still evolving and continuing to change rapidly, NHTSA will not attempt to establish further minimum performance criteria for this function at this time. Accordingly, at the present time, NHTSA will continue to include Tests 9c–f in the revised Model Specifications.

Test 10—Restart of Stalled Motor Vehicle

Comments received in response to the 2006 notice suggested that restarts should be allowed only if a vehicle stalls, but not if the ignition is intentionally turned off or if a BAIID malfunctions or is awaiting a retest. In the 2010 notice, NHTSA proposed that a restart (i.e., without a breath sample) should be allowed when the vehicle stalls, provided the restart is accomplished in no more than 20 seconds. NHTSA also proposed that in all other situations where the vehicle malfunctions, the vehicle should be prevented from starting without a breath test. (75 FR 61825.)

The agency received a number of comments in response to this aspect of the proposal, all of which were in

opposition. The comments uniformly argued that a period of 20 seconds is too short and could create unnecessary safety risks, particularly if a vehicle stalls in a hazardous area. Draeger pointed out that panic often occurs in a critical stall situation. (p. 5.) IISI asked whether NHTSA had received any reports that warranted a reduction in the ''3 minute time period * * * by nearly 90% to 20 seconds.'' (p. 3.)

NHTSA acknowledges that stalls can take place in locations, such as on railroad tracks or in heavy traffic, which could present serious hazards should a driver be unable to restart the vehicle. While the comments suggested a variety of counter-proposals, ranging from 1–3 minutes, NHTSA notes that no comments, in response to either the agency's 2006 notice or its 2010 notice objected to the 3 minute time period contained in the 1992 Model Specifications. Accordingly, the agency has decided to retain the time period of 3 minutes.

Test 11—High Altitude

The 2010 notice proposed the addition of a high altitude test and proposed that it would apply only to BAIIDs using semiconductor alcohol sensors, based on a belief that high altitudes affect these types of sensors. (75 FR 61826, 61829.) Some comments objected to this unequal treatment. ACS did not object to inclusion of this test, but recommended that it be applied to all alcohol interlocks submitted for conformance testing. (p. 34.) CST asserted that this high altitude test is warranted also for fuel cell devices, but urged that ''semiconductor technology should be outlawed'' altogether. (p. 5.)

As explained earlier in this notice in Section II.B.1., the agency will not specify particular types of technology that should or should not be used. Instead, the Model Specification specify performance criteria to be met. To ensure consistent treatment of all instruments and to anticipate the possibility of other instruments that might be introduced into the marketplace, all BAIIDs should be tested under these high altitude conditions.

Test 12—Cigarette Smoke

This proposed test would require a person who is alcohol-free to smoke approximately ½ of a cigarette, and wait one minute or a period specified by the BAIID manufacturer before testing. The proposal indicated that a simulator may be used in lieu of a smoker. (75 FR 61829.) ACS objected to this proposed test, stating ''This is not a performance test equally applied to all BAIIDs if the manufacturer can specify how long to wait after the person smokes the cigarette.'' ACS suggested instead that the test should specify, for example, that 30 seconds be applied equally to all BAIIDs. (p. 34.) NHTSA disagrees. Like some other elements of these Model Specifications, some conformance tests should be conducted in accordance with the manufacturer's user instructions. If a manufacturer instructs users that they must wait 10 minutes after smoking a cigarette before they may use the BAIID, Test 12 should be conducted in accordance with those instructions. We note, however, that a BAIID that imposes this sort of limitation on the user may experience disadvantages in the marketplace. This aspect of Test 12 has been clarified, by specifying that the test should be conducted in accordance with the manufacturer's user instructions.

ACS also asked about the possible use of a simulator to conduct this test. Specifically, ACS asked how the test would simulate a person who smokes ½ a cigarette and then wait a fixed period of time. (p. 34.) NHTSA no longer believes that a simulator needs to be used for the cigarette smoke test. Accordingly, reference to a simulator in this portion of the Model Specifications has been deleted. No other comments objected to this proposed test. It is otherwise adopted without change.

Test 13—Acetone

The 2010 notice proposed adding an acetone test, based on NHTSA's belief that it is the most common interfering substance for BAIIDs. (75 FR 61826.) No comments objected to the inclusion of this test, although CST noted that ''the concentration being used for the test is higher than would be experienced by a diabetic about to go into a diabetic coma, and thus . . . does not really reflect real world conditions.'' (p. 5.) Wisconsin noted that alcohol-specific sensors, such as fuel cells, will have no difficulty passing this test, since substances other than alcohol will have no effect. However, Wisconsin urged that units that are not specific to alcohol, such as semi-conductors, ''should be rigorously tested for the impact of interferences such as acetone and other volatile organic compounds.'' (p. 5.)

This test has been adopted with a lower concentration of acetone (115 microliters, rather than 230), which is a more realistic level. The test should be applied to all BAIIDs. No other changes have been made.

Test 14—Emergency Override

This issue was discussed fully in Section II.B.5. NHTSA believes the decision whether to permit the use of an emergency override feature is programmatic in nature and should be left to the discretion of States and local jurisdictions. Accordingly, as proposed, the Model Specifications do not specify that BAIIDs be equipped with an emergency override feature in order to meet the Model Specifications. Since this feature is not specified, the Model Specifications will not include a test of this feature. The Model Specifications are modified to eliminate the reference to a feature that prevents an override from being used when the BAIID malfunctions or fails and it removes proposed Test 14.

Test 15—Radiofrequency Interference/Electromagnetic Interference

In the 2006 notice, NHTSA explained that the RFI testing protocol in the 1992 Model Specifications uses power sources that are no longer commonly in use, but noted that new power sources that may interfere with the operation of BAIIDs (e.g., cell phones) have output power commensurate with equipment in use today. The agency asked what are the appropriate levels to measure RFI/EMI. (71 FR 8048.)

The comments pointed out that an increasing number of electronic devices are being operated in close proximity to BAIIDs, such as gaming, remote keyless entry, portable medical and Bluetooth-capable devices. The comments offered a variety of recommendations to address these potentially interfering power sources.

In the 2010 notice, NHTSA expressed its belief that the current specifications do not adequately define or describe RFI/EMI tests and proposed to test BAIIDs for emissions and transmissions of RFI/EMI and immunity to RFI/EMI using the SAE Surface Vehicle Standard J1113 series for Class C devices (devices essential to the operation or control of the vehicle) and the International Special Committee on Radio Interference (CISPR), Subcommittee of International Electro-technical Committee (IEC); specifically, CISPR 25, for RFI/EMI testing. NHTSA stated that it believed these procedures represent a broad consensus in the industry. (75 FR 61823.)

The agency received comments regarding this test from Smart Start, ACS, LifeSafer, ADS, CST and the State of Wisconsin. Most of the comments supported the proposed tests, although CST expressed the belief that the tests may be unnecessary. (p. 5.) ADS recommended that the appropriate level for testing should be 1W or less, since that level would be sufficient to identify potential cell phone interference. (p. 2.)

Wisconsin recommended that immunity testing for electrical equipment should be conducted in conformity with EN 61326–1:2001. (p. 5.)

The agency has not changed these elements of the Test. NHTSA believes the tests should not be limited to cell phone interference. The EN 61326–1:2001 test cited in Wisconsin's comment is used for remote locations, such as bridges, roads, etc., and not for motor vehicles.

Test 16—Service Interval Display

As discussed more fully in Section II.B.6. and in the discussion regarding Test 3, NHTSA agrees that it is appropriate to decouple the period of calibration stability and the service interval. States and local jurisdictions make decisions about service intervals based on a number of different factors, including the need to supervise some offenders more closely or the desirability of providing an incentive (and permitting a longer service interval) for offenders who have demonstrated compliance with their sentence. In addition, NHTSA recognizes that BAIIDs can be programmed to vary the service interval, based on the circumstances in each case. Accordingly, the Model Specifications do not provide for a specific service interval period. Rather, the agency defers to States and local jurisdictions to determine the service intervals they believe are appropriate.

However, Test 16 has a different function. Its purpose is to ensure that the BAIID's display of the service interval is working properly. While NHTSA recognizes that service intervals may be set at a variety of time periods, the Model Specifications provide that a period of 30 days (with a 7-day lockout countdown) should be used for the purpose of this test. Under Test 16, after a period of 30 days, the BAIID should prominently display that the vehicle be taken to a designated maintenance facility for maintenance and data downloads within seven days. This message should continue to be displayed for seven days. Following the seven-day period, if the BAIID is not serviced at a designated maintenance facility, it should not allow the vehicle to be started.

Test 17—Data Integrity and Format

NHTSA proposed that the data be downloaded from the interlock data logger after all other tests have been completed. (75 FR 61831.) No comments objected to this requirement.

D. Other Comments Received Regarding the Model Specifications

1. Dust Test

In the 2010 notice, NHTSA indicated that one comment to the 2006 notice had suggested that several CENELEC standards be adopted into the Model Specifications, including the dust standard. The agency responded that in two decades of experience, NHTSA has received no reports suggesting that dust is an issue or source of concern in BAIIDs installed in vehicles. Accordingly, NHTSA did not propose to include a dust standard in the Model Specifications. (75 FR 61826.) A number of comments specifically agreed with the agency's decision, including Smart Start and IISI. A dust standard has not been added.

2. Vehicle-Interlock Interface

The 2006 notice indicated that anecdotal reports from ignition interlock manufacturers have suggested that it is sometimes difficult to install existing interlock systems in some of the newer electronic ignition systems. The agency asked whether NHTSA should establish any guidelines regarding the vehicle-interlock interface. (71 FR 8048.)

The comments received in response were mixed. In general, interlock manufacturers and providers supported a standard interlock-vehicle interface; vehicle manufacturers asserted that requiring a common interface presented significant challenges that could compromise vehicle ignition security systems and anti-theft immobilizing technologies. In the 2010 notice, NHTSA acknowledged that a common interface could afford installation convenience. However, the agency indicated that it would not specify such a requirement in the Model Specification and explained that ''such a requirement goes beyond the scope of this proposal, which is limited to the BAIID itself and not to changes to the vehicle.'' (75 FR 61823–24.)

The comments received in response to this issue were mixed. For example, National Interlock asked NHTSA to reconsider its decision and establish specifications regarding a common interface. (p. 1.) ADS said it would support this type of provision. (p. 2.) CST agreed with the vehicle manufacturers that a common interface could compromise anti-theft systems and should not be required. (p. 7.) Draeger expressed its view that requiring a specific interface on all vehicles might be impractical. (p. 3–4.) ACS agreed with the agency that the interface is beyond the scope of these Model Specifications. (p. 12.) CIIM argued that, ''As advances in the automobile industry evolve, installation of interlock devices becomes more difficult. There are examples of installations taking hours, even days to complete as remote starters and push button ignitions become more prevalent.'' CIIM urged NHTSA to ''facilitate a dialogue between the two industries about this issue.'' (p. 3.)

NHTSA will take CIIM's recommendation under advisement. However, the agency continues to believe that a common interface in vehicles for ignition interlocks is outside the scope of these Model Specifications. Accordingly, the agency has not included such a requirement in this notice.

3. International Harmonization

In the 2006 notice, NHTSA asked about the importance of harmonizing NHTSA's Model Specifications for BAIIDs with standards in other parts of the world. (71 FR 8048.) The comments received in response to this aspect of the notice were varied. Some comments supported harmonization with CENELEC (the European standard) due to increasingly global economy; others opposed harmonization based on a belief that aspects of the CENELEC standard are potentially restrictive and costly. In response, NHTSA proposed to maintain an independent set of Model Specifications, but to incorporate selected elements of the CENELEC, including vibration and cigarette smoke. (75 FR 61825.)

As noted above, the comments favored inclusion of these tests and some comments suggested that other CENELEC tests be included as well, including high temperature, dust and the drop test.

NHTSA has carefully considered other standards, including CENELEC, and as appropriate, has incorporated consistent provisions into these Model Specifications. In some cases, variations are warranted, based on cost, conditions and the manner in which BAIIDs are used in the United States. Further discussions regarding individual tests are contained in other sections of this notice.

4. Ignition Interlock Program Guidelines

In the 2006 notice, NHTSA asked whether the ignition interlock community (users, manufacturers, States, etc.) favor NHTSA development of an ''interlock program'' in addition to Model Specifications for devices. (71 FR 8048.) Some comments supported the development of ignition interlock program guidelines; others expressed the belief that program guidelines have

been and should remain a function of State government.

NHTSA did not include program guidelines in the 2010 notice, but indicated that the agency may explore the development of such guidelines in the future. (75 FR 61825.) The comments generally supported this position. AAMVA urged NHTSA to ensure that any such guidelines are ''based on scientifically valid research'' and ''allow the necessary flexibility.'' (p. 1.)

As stated earlier in this notice, NHTSA is committed to providing support, and not dictating practices, to the States. Over the last few years in particular, the agency has sought to provide information, support and technical assistance to the States in a variety of ways. NHTSA hosted a National Ignition Interlock Summit and invited representatives from every State to attend. NHTSA has also produced a number of publications containing information about ignition interlock programs, including ''Ignition Interlocks—What You Need to Know: A Toolkit for Policymakers, Highway Safety Professionals and Advocates'' (DOT HS 811 246), ''Key Features for Ignition Interlock Programs'' (DOT HS 811 262), National Ignition Interlock Summit Proceedings'' (available on *www.ghsa.org*) and a series of New Mexico ignition interlock studies (see Traffic Tech 401; November 2010). In addition, NHTSA supported the development of the Alcohol Interlock Curriculum for Practitioners by the Traffic Injury Research Foundation (TIRF) (available on *www.tirf.ca*) and has supported technical assistance workshops, meetings and training (in cooperation with TIRF) and a series of regional Ignition Interlock Summits (in cooperation with Mothers Against Drunk Driving). Also, NHTSA has provided financial assistance to support the establishment of a new National organization, representing State Ignition Interlock Program Administrators.

NHTSA will continue to provide support and assistance to States as they seek to expand and strengthen their ignition interlock programs, and the agency will consider whether the development of program guidelines would add value to the field. However, such guidelines are outside the scope of this notice and have not been included in the Model Specifications.

E. NHTSA Testing of BAIIDs and Conforming Products List (CPL)

In the 2006 notice, the agency asked, whether NHTSA should undertake the responsibility to evaluate ignition interlocks against its Model Specifications and publish a CPL of devices meeting those specifications. (71 FR 8048.)

In the 2010 notice, in response to comments received, NHTSA explained that the comments favored a certified testing laboratory program. Most advocated a NHTSA test program and the development of a CPL based on the Model Specifications. One commenter favored having a single private testing laboratory certified by NHTSA for this purpose. Several manufacturers noted significant problems with State certification requirements leading to questionable test results for some products. In general, both manufacturers and States favored a NHTSA test program because it would organize and standardize the industry and exclude less effective BAIIDs. One commenter suggested that NHTSA require BAIID re-certification in the event of an instrument design change and/or at some reasonable interval. (75 FR 61824.)

In the 2010 notice, NHTSA proposed to test BAIIDs for conformance with the Model Specifications. NHTSA also proposed to maintain and publish periodically a CPL with BAIIDs that have been tested and found to conform to the Model Specifications. NHTSA proposed to manage this new program as it does its other breath alcohol instrument testing programs. (75 FR 61824.)

NHTSA explained that testing of BAIIDs will be subject to the availability of Federal funds. If Federal funds are not available, NHTSA will discontinue testing BAIIDs until funds become available. (75 FR 61825.) In the proposed Submission Procedures contained in Appendix A of the 2010 notice, NHTSA proposed that it would ''test BAIIDs on a first-come, first-served basis.'' (75 FR 61831.)

More than half of the comments addressed this issue and many of them raised concerns, though the concerns expressed were varied. Some of the comments related to the potential of insufficient funds and whether Volpe has the capacity to conduct the testing. For example, Oklahoma stated, ''We cannot support the limitation that 'All tests are subject to the availability of Federal funds.' '' (p. 2.) ACS asserted that ''Volpe Laboratories lacks the equipment, expertise and perhaps financial resources to conduct the range of qualification tests on alcohol interlocks for conformance with the Model Specifications.'' (p. 16.) The comments offered various possible solutions to address these concerns, including that the manufacturers fund the testing of BAIIDs (Smart Start), that there be a funding limitation (Draeger) or that NHTSA consider certifying independent laboratories to perform some or all of the testing (ACS, Alcohol Detection Systems, Draeger, Guardian, National Interlock, Coalition of Ignition Interlock Manufacturers).

In general, the comments were supportive of a NHTSA CPL. Guardian's comments were typical. They stated, ''whether the test results are provided by NHTSA or by [an outside laboratory], a conforming product should be placed on the NHTSA conforming products list.'' Guardian asserted further, ''If NHTSA cannot agree to this critical element, then there should NOT be a CPL for these products.'' (p. 2.)

While some comments seemed to express alarm about the statement in the 2010 notice that the testing program would be subject to the availability of funds, this limitation applies to all Federal programs, including NHTSA's current testing programs for evidential breath testers, calibrating units and other breath alcohol instruments and devices.

The Volpe National Systems Center is currently in the process of developing the capacity to conduct Radiofrequency Interference (RFI) and Electromagnetic Interference (EMI) testing. Volpe is capable of conducting all other tests delineated in the Model Specifications. NHTSA expects that Volpe will have the ability to conduct the RFI/EMI tests in the near future. Until then, Volpe has the ability to procure these tests from other qualified laboratories.

However, the comments raise a valid concern about the ability of any one laboratory, including Volpe, to test all available BAIID models in a sufficiently timely manner, especially during the initial period when these revised Model Specifications will initially go into effect. The agency also appreciates the concern that some comments expressed regarding the testing of BAIIDs on a first-come, first-served basis. The agency does not wish to take any steps that would create an unfair competitive advantage for some manufacturers over others.

Since these revised Model Specifications represent a substantial departure from the existing 1992 specifications, NHTSA will delay rendering a decision about the feasibility and timing of a CPL until more information is available about the implications for testing costs, resource requirements and the time necessary to conduct product testing.

Accordingly, NHTSA plans to conduct an assessment to determine whether establishing and maintaining a CPL is feasible, prior to rendering a decision.

If the agency determines that a CPL is feasible, NHTSA will announce its intention to develop a CPL in a **Federal Register** notice and will, at that time, outline the procedures that will apply, including steps for submitting BAIIDs for compliance testing. The agency would seek to establish procedures that ensure a level playing field, in terms of competition among ignition interlock manufacturers.

Accordingly, NHTSA expects that manufacturers will continue to certify, and States and local jurisdictions will continue to determine, that BAIIDs conform to the Model Specifications essentially in the same manner that is currently being used. However, the revised Model Specifications, rather than the 1992 version, should be used, once they become effective. The Model Specifications will not take effect immediately, but rather will be delayed for one year, to provide manufacturers of BAIIDs sufficient time to make conforming modifications to their instruments and to conduct testing, as warranted.

F. Appendices to the 2010 Notice

The 2010 notice contained four appendices. Appendix A included submission procedures for conformance testing of BAIIDs. (75 FR 61831.) Appendix B included procedures for the re-examination of BAIIDs, which occur at the sole discretion of NHTSA. (75 FR 61831–32.) Appendix C provided a template for a Quality Assurance Plan. (75 FR 61832.) Appendix D provided a sample format for downloaded data from the interlock data logger. (75 FR 61832–33.)

As explained above, NHTSA has not yet decided whether it will develop a CPL. It will first conduct an assessment to determine its feasibility. If the agency decides that a CPL is feasible, NHTSA will publish a **Federal Register** notice announcing its plans to proceed and will, at that time, outline the procedures that will apply.

Accordingly, the first two appendices that were contained in the 2010 notice (then identified as Appendix A and Appendix B) are not included in this notice. The other two appendices that were contained in the 2010 notice (then identified as Appendix C and Appendix D) have been renamed as Appendix A and Appendix B, respectively.

III. New Model Specifications

On October 6, 2010, NHTSA proposed revisions to the 1992 Model Specifications for BAIIDs. (75 FR 61820.) Those proposed revisions were based, in part, on input from the comments received in 2006. Today, in response to the October 6, 2010 notice, the 1992 Model Specifications have been revised.

This Notice is not intended to take the place of any State certification requirements; rather, it provides for a voluntary testing and conformance program.

These Model Specifications do not have the force of regulations and are not binding. States and others may adopt these Model Specifications and rely on any tests that NHTSA may conduct, or they may conduct their own tests according to their own procedures and specifications.

After consideration of the comments, the Model Specifications for Breath Alcohol Ignition Interlock Devices have been revised to reflect the decisions discussed above and are set forth below.

Authority: 23 U.S.C. 403; 49 CFR 1.95; 49 CFR Part 501.

MODEL SPECIFICATIONS FOR BREATH ALCOHOL IGNITION INTERLOCK DEVICES (BAIIDs)

A. Purpose and Scope

The purpose of these specifications is to establish recommended performance criteria and test methods for breath alcohol ignition interlock devices (BAIIDs), commonly referred to as alcohol interlocks or ignition interlocks. BAIIDs are breath alcohol sensing instruments designed to prevent the motor vehicle from starting unless the driver first provides a breath sample whose alcohol concentration is below the set point into the BAIID. If the measured breath alcohol concentration (BrAC) is at or above a set level, the vehicle will not start. BAIIDs are currently being used as court sanctions as well as administrative conditions of licensure. Drivers convicted of impaired driving may be required to use BAIIDs in their vehicle under court supervision or as part of a required path to full reinstatement of driving privileges. These specifications are intended for use in conformance testing of BAIIDs installed in vehicles. These specifications are voluntary and do not impose any compliance obligations on BAIID manufacturers or others.

B. Terms

Alcohol—Ethanol or ethyl alcohol (C_2H_5OH).

Alcohol set point—Breath Alcohol Concentration (BrAC) at which a BAIID is set to prevent a vehicle from starting.

Breath Alcohol Concentration (BrAC)—The amount of alcohol in a given amount of breath, expressed in weight per volume (w/v) based upon grams of alcohol per 210 liters (L) of breath, in accordance with the Uniform Vehicle Code, Chapter 11, Section 11–903.4 and 5.[1]

Breath alcohol ignition interlock device (BAIID)—A device that is designed to allow a driver to start a vehicle if the driver's BrAC is below the set point and to prevent the driver from starting the vehicle if the driver's BrAC is at or above the set point.

Breath Sample—Normal expired human breath primarily containing air from the deep lung.

Calibration Stability—The ability of a BAIID to hold its accuracy and precision over a defined time period.

Circumvention—An attempt to bypass the correct operation of a BAIID, whether by use of an altered breath sample, by starting the vehicle by any means without first providing a breath sample.

Filtered air sample—Any human breath sample that has intentionally been altered so as to remove alcohol from it.

Interlock Data Logger—A device within a BAIID that records all events, dates, and times during the period of installation and use of a BAIID.

Retest—A breath test that is required after the initial engine start-up breath test and while the engine is running. This is also referred to as a running retest.

Service Interval—The time period established by the State or jurisdiction that a BAIID may be used without maintenance or data download. If the device is not serviced within the period, warnings are provided and the device will prevent further operation.

Simulator—A device that produces an alcohol-in-air test sample of known concentration (e.g., a Breath Alcohol Sampling Simulator (BASS))[2] or a device that meets the NHTSA Model Specifications for Calibrating Units (72 FR 34742)).

Tampering—An attempt to physically disable, disconnect, adjust, or otherwise alter the proper operation of a BAIID.

C. General Provisions and Features of BAIIDs

Conforming BAIIDs must meet the following provisions:

The BAIID must pass each of the conformance tests 1 through 16 in Section D, unless explicitly excluded from a test by the specific terms of these specifications.

[1] Available from the National Committee on Uniform Traffic Laws and Ordinances, 107 South West Street, #110, Alexandria, VA 22314 (*http://www.ncutlo.org*).

[2] See NBS Special Publication 480–41, July 1981. Available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

Installation and service of the BAIID in a vehicle must not compromise any normal function of the vehicle, including anti-theft functions, on-board computer functions, or vehicle safety features required by the Federal Motor Vehicle Safety Standards, and must not cause harm to the vehicle occupants. Care should be taken to protect against reverse polarity and damage to other circuits and to ensure that the BAIID does not drain the vehicle's battery while in sleep mode (i.e., power save mode).

The BAIID must have tamper proof seals to indicate when a BAIID has been disconnected from the ignition.

The BAIID must be capable of permitting a vehicle to start or preventing it from starting at specified breath alcohol concentrations.

The BAIID must be tested at an alcohol set point of 0.02 g/dL with a flow rate of 0.3 L/sec. Upon detecting an alcohol concentration at or above that set point, the BAIID must prevent the vehicle from starting for a period of time before another test can be performed.

If the vehicle is equipped with a remote start device, the BAIID must be installed so that the remote start function is bypassed or disabled and a valid breath test must be performed before the vehicle may be started.

If the BAIID has a removable sensing head, the BAIID may not allow the vehicle to start without use of the sensing head.

The BAIID must include clear instructions to the driver (e.g., when to blow, when to wait, when to start the vehicle, when to retest, when a lockout countdown occurs, including the time remaining before the BAIID may be used again to start the vehicle, and when to seek service).

Manufacturers must submit the operator's manual (user's guide or instructions to the user), the maintenance manual, and specifications and drawings fully describing the BAIID.

In addition, manufacturers must submit the quality assurance plan (QAP). The QAP must include the following information: instructions for checking the calibration of the BAIID (i.e., recommended calibrating unit, BrAC of 0.02 g/dL, agreement not greater than ±0.005 BrAC, verification of accuracy of readout, actions to take for failed calibration check), instructions for downloading the data from the interlock data logger, instructions to maintain the BAIID, instructions on checking for tampering, and any other information regarding quality assurance unique to the BAIID. See Appendix A for a sample QAP template.

The design of the BAIID must include an interlock data logger that will record, at a minimum, all start attempts and outcomes, including an emergency override if applicable, delineation of calibration checks, circumvention, tampering, operator attempts to start the vehicle, and BrAC for each start attempt. The data must be presented in chronological order (i.e., by date and time of event). See Appendix B for a sample format for downloaded data from the interlock data logger. The manufacturer must provide a means of downloading the data from the interlock data logger.

Any change to a BAIID that could affect its performance, including potentially software changes, should require additional testing. The BAIID must track all changes to the metrological software and indicate the software version and date on all printed and downloaded reports. NHTSA is aware that States (and local jurisdictions) use different set points in their interlock programs, and changes to the set point, alone, would not require additional testing. The Model Specifications provide that BAIIDs are to be tested at an alcohol set point of 0.02 g/dL.

D. BAIID Test Procedures

General Test Conditions

Unless otherwise specified in a conformance test, the following conditions apply to each test:

- Number of trials at each alcohol level = 20
- Ambient temperature: 22 °C ± 3 °C (71.6 °F ± 5.4 °F).
- Ambient atmospheric pressure: 97.5 kPa ± 10.5 kPa (25.7 and 31.9 inches Hg).
- Sample parameters: volume 1.2 liters; ambient flow rate 0.3 Liters per second; maximum delivery pressure 2.5 kPa; temperature 34 °C (93.2 °F)
- Simulated breath samples will be generated by the BASS [3] or by a wet bath type calibrating unit that is listed on the NHTSA Conforming Products List for such devices. Solutions used in the calibrating device will be prepared as described in the NHTSA Model Specifications for Calibrating Units published June 25, 2007 (72 FR 34742).

Performance Requirements

Unless otherwise specified in a conformance test, the BAIID must meet the following performance requirements in each test:

- Tests at 0.000 g/dL BrAC: the vehicle must not be prevented from starting during 20 trials.
- Test at 0.008 g/dL BrAC: the vehicle must not be prevented from starting more than once during 20 trials.
- Tests at 0.032 g/dL BrAC (grams alcohol/210 liters of air): the vehicle must not start more than once during 20 trials.
- A BAIID must be ready for use 3 minutes or less after it is turned on. A BAIID must be ready for a second test within 3 minutes or less of a preceding test.

Conformance Tests

Unless otherwise specified in a test, these conformance tests need not be conducted in any particular order. Except when a test or portion of a test specifically requires the use of a motor vehicle, either a motor vehicle or a bench test set-up that simulates the relevant functions of a motor vehicle may be used.

Test 1. Precision and Accuracy

Test the BAIID at the following alcohol concentrations:

a. 0.000 g/dL BrAC,
b. 0.008 g/dL BrAC, and
c. 0.032 g/dL BrAC.

Test 2. Breath Sample Volume and Flow Rate

Use a mass flow meter to monitor sample volume. Conduct each test (a–d) five times.

a. Test at 0.000 g/dL BrAC with sample volume 1.0 liter. The BAIID must prevent the vehicle from starting and indicate insufficient volume 5 out of 5 times.

b. Test at 0.000 g/dL BrAC with sample volume 1.5 liters. The BAIID must permit the vehicle to start 5 out of 5 times.

c. Test at 0.000 g/dL BrAC with sample volume 1.2 liters at 0.1 L/s. The BAIID must prevent the vehicle from starting 5 out of 5 times.

d. Test at 0.000 g/dL BrAC with sample volume 1.2 liters at 0.7 L/s. The BAIID must permit the vehicle to start 5 out of 5 times.

Test 3. Calibration Stability

Initialize the BAIID to begin the calibration stability test. A BAIID must not be re-calibrated after the start of Test 3. Conduct Test 1. Repeat Test 1 at 37 days. Test 2 and Tests 4–15 may be performed between these two Precision and Accuracy tests.

If requested by the manufacturer, repeat Test 1 at 67 days, 97 days and 187 days. These additional tests are optional. They exceed the minimum requirements of this test.

[3] See NBS Special Publication 480–41, July 1981. Available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

Test 4. Input Power

Conduct Test 1b and Test 1c at the following input power conditions:

a. Test at 11 VDC input power.

b. Test at 16 VDC input power.

Test 5. Extreme Temperature and Humidity

Using a temperature/humidity chamber:

a. Soak the BAIID at −40 °C (−40 °F) for 1 hour, then conduct Test 1b and Test 1c at that temperature using 9 VDC input power.

b. Soak the BAIID at 49 °C (120 °F), 95 percent relative humidity for 1 hour, then conduct Test 1b and Test 1c at that temperature and humidity using 16 VDC input power.

c. This part of the test applies only to BAIIDs with components installed in the engine compartment. Soak the components of the BAIID that are installed in the engine compartment at 85 °C (185 °F), 95 percent relative humidity for 1 hour, then conduct Test 1b and Test 1c at that temperature and humidity using 16 VDC input power. The components that are installed in the passenger compartment should remain at ambient temperature and humidity conditions. Removable components will be tested in accordance with the manufacturer's instructions to the user. (See General Test Conditions).

Test 6. Warm Up Time at −40 °C

Using a temperature chamber, soak the BAIID for 1 hour at −40 °C. With input power set at 9 VDC, the BAIID must be ready to test in 3 minutes, and ready to retest in 3 minutes after being turned on. Conduct Test 6 five times. The BAIID must indicate that it is ready to test or ready to retest in 3 minutes all five times. This test may be conducted in conjunction with Test 5 Extreme Temperature and Humidity.

Test 7. Vibration

Vibrate the BAIID in simple harmonic motion on each of three main axes uniformly through the frequency schedule specified below. For components not intended to be mounted on the engine, vibrate according to Test 7a; for components intended to be mounted on the engine, vibrate according to Test 7b. If a BAIID consists of several components connected by electrical wires or connected wirelessly, vibrate these components separately. After completion of the vibration, remove the BAIID from the shake table and conduct Test 1b and Test 1c.

VIBRATION FREQUENCY SCHEDULE

Test 7	Frequency range, Hz	Number of cycles	Sweep rate, octave/min	Amplitude, inches 0 to peak	Acceleration, gravity (g), 0 to peak
a	10 to 500	10	1	0.2	3
b	10 to 500	10	1	0.08	15

Test 8. Retest

If a BAIID includes a feature designed to detect whether the vehicle is moving, conduct Test 8 using a motor vehicle. If a BAIID does not include a feature designed to detect whether the vehicle is moving, conduct Test 8 using a motor vehicle or a bench test set-up that simulates the relevant functions of a motor vehicle.

a. Within an interval of 5 to 7 minutes after a vehicle successfully starts, using a 0.000 g/dL BrAC test sample, and while the engine is still running, the BAIID must indicate that a second breath sample is required. Conduct Test 1b five times. The BAIID must treat this test as a passed retest all 5 times.

b. Within an interval of 5 to 7 minutes after a vehicle successfully starts, using a 0.000 g/dL BrAC test sample, and while the engine is still running, the BAIID must indicate that a second breath sample is required. Conduct Test 1c five times. The BAIID must treat this test as a failed retest and prominently indicate the need for a service call.

A failed retest must be identified as an alert condition and flagged on the interlock data logger. A missed retest must be flagged on the interlock data logger. After the driver is alerted to retest, if the engine is accidentally or intentionally powered off, the BAIID must not allow the vehicle to start without a service call.

Test 9. Tampering and Circumvention

Attempt to start the ignition as indicated below. Conduct each test (a through f) five times. Each attempt to start the engine must be logged by the interlock data logger.

a. *''Hot wiring''.* Start the engine by electrically bypassing the BAIID. The interlock data logger must record the ignition on with no breath test.

b. *Push start.* A motor vehicle must be used for this part of Test 9. Use a vehicle equipped with a manual transmission. Start the engine by pushing the vehicle with another vehicle or by coasting the vehicle downhill before engaging the clutch. The vehicle must run for at least two minutes. The interlock data logger must record the ignition on with no breath test.

c. *Un-warmed air sample.* Deliver an alcohol-free air sample of at least 2 liters into the BAIID using an air filled plastic bag which is fitted to the sampling tube and squeezed in a manner that mimics a person blowing into the BAIID. The vehicle must not start.

d. *Warmed air sample.* Prepare a 12-ounce foam coffee cup fitted with a bubble tube inlet and a vent tube (rubber or tygon tubing) attached through the plastic lid. Fill the cup with 8 ounces of water warmed to 36 °C and attach the lid. Attach the vent tube to the BAIID and pass an air sample of at least 2 liters through the bubble tube into the heated water and thence into the BAIID. The flow rate must not be high enough to cause a mechanical transfer of water to the BAIID. The vehicle must not start.

e. *Cooled 0.032 BrAC sample.* Attach a 4 foot long tygon tube of ⅜ inch inside diameter which has been cooled to ice temperature to the inlet of the BAIID, then test at 0.032 BrAC. The vehicle must not start.

f. *Filtered 0.032 BrAC sample.* Prepare a 1 to 2 inch diameter 3 to 5 inches long paper tube loosely packed with an active absorbent material. Use loose cotton plugs to retain the absorbent in the paper tube. Pack the tube so that a person can easily blow 2 liters of air through the assembly within 5 seconds. Test the absorbent by passing a 2 liter 0.032 BrAC sample though the assembly within 5 seconds. If the air passing out of the BAIID is found to have a concentration of 0.006 BrAC or less, prepare 5 tubes packed in the same manner, fit separately to the BAIID and test at 0.032 BrAC. The vehicle must not start.

g. *Alternative to Tests 9c—9f.* If a BAIID includes an anti-circumvention feature designed to ensure that the driver is blowing into the BAIID, test its operation at 0.000 BrAC in lieu of tests 9c—9f.

Test 10. Restart of Stalled Motor Vehicle

Conduct Test 10 using a motor vehicle.

Using a 0.000 g/dL BrAC sample, turn on the ignition. Turn off the ignition. Attempt to restart the ignition without a breath sample in less than 3 minutes—the vehicle must start. Turn off the ignition. Attempt to restart the ignition without a breath sample within 3 minutes after turning off the ignition—the vehicle must not start. Conduct Test 10 five times.

Test 11. High Altitude

Conduct Test 1b and Test 1c each at pressures of 80 kPa and 110 kPa (600 mmHg and 820 mmHg). Conduct Test 11 five times at each indicated pressure. At indicated pressure levels, for Test 1b, the ignition must treat the test as a passed test; for Test 1c, the ignition must treat the test as a failed test.

Test 12. Cigarette Smoke

Direct a cigarette smoker, who is alcohol-free, to smoke approximately ½ of a cigarette. The smoker must wait 1 minute or the period specified by the BAIID manufacturer in its user instructions before testing. Conduct Test 12 three times. The vehicle must start.

Test 13. Acetone

Test the BAIID for acetone interference. Conduct Test 1b by adding 115 microliters of acetone [4] to the 500 milliliters of .008 g/dL BrAC alcohol simulator solution. Conduct Test 1b three times. The vehicle must start.

Test 14. Radiofrequency Interference (RFI)/Electromagnetic Interference (EMI)

The Society of Automotive Engineers (SAE) Surface Vehicle Standard J1113 series, Required Function Performance Status, as defined in Surface Vehicle Standard J1113–1 for Class C devices (devices essential to the operation or control of the vehicle), and the International Special Committee on Radio Interference (CISPR), Subcommittee of International Electrotechnical Committee (IEC), specifically CISPR 25, will be used to evaluate BAIID electromagnetic immunity and compatibility. The test severity levels are specified below. The tests must be performed while the BAIID is in the drive and standby modes.

a. *J1113–1* 2006–10 General and definitions. Electromagnetic Compatibility Measurement Procedures and Limits for Vehicles, Boats, and Machines (Except Aircraft) (16.6 Hz to 18 GHz).

b. *J1113–2* 2004–07 Conducted immunity 30 Hz to 250 kHz—Power leads.

Level	Severity (volts, peak to peak)	Status
1	0.15	I
2	0.50	I
3	1.0	I
4	3.0	II

c. *J1113–4* 2004–08 Conducted immunity—Bulk Current Injection (BCI) Method.

Level	Severity (milliamps)	Status
1	25 to 60	I
2	60 to 80	II
3	80 to 100	III
4	100	IV

d. *J1113–11* 2007–06 Immunity to Conducted Transients on Power Leads.

Pulse (12 v sys)	Level	Severity (volts)	Status
1	1	−25	I
	2	−50	II
	3	−75	II
	4	−100	IV
2a	1	25	I
	2	40	II
	3	50	II
	4	75	IV
2b	1	10	I
3a	1	−35	I
	2	−75	II
	3	−112	II
	4	−150	IV
3b	1	25	I
	2	50	II
	3	75	II
	4	100	IV
4	1	−4	I
	2	−5	II
	3	−6	II
	4	−7	IV
5	1	87	IV

e. *J1113–13* 2004–11 Part 13: Immunity to Electrostatic Discharge.

Severity	Status
Contact discharge	
0–4 kV	I
4–8 kV	II
8 kV	IV
Air discharge	
0–4 kV	I
4–15 kV	II
15 kV	IV

f. *J1113–21* 2005–10 Immunity to Electromagnetic Fields, 30 MHz to 18 GHz.

Severity (V/M)	Status
Up to 60	I
60–80	II
80–100	III
100–150	IV

g. *J1113–22* 2003–11 Immunity to magnetic fields

Severity (uT)	Status
40	I
40–50	II
50–80	III
80	IV

h. *IEC CISPR 25* Limits of Radio Disturbance.

RADIATED DISTURBANCE LIMITS

[1 M test distance, 120 kHz bandwidth]

	30–75 MHz	75–400 MHz	400–1000 MHz
a	62 − 25.13 × log(F/30)	52 + 15.13 × log(F/75)	63
b	52 − 25.13 × log(F/30)	42 + 15.13 × log(F/75)	53

a: broadband, quasi-peak detector.
b: narrowband, average detector.
limit in dB (uV/M) at frequency F.

[4] The amount of acetone specified is experimentally determined based on water to air partition factor of 365 to 1 at 34 °C to yield an acetone concentration in the air sample of 0.5 mg/liter.

CONDUCTED TRANSIENT EMISSIONS

Pulse polarity	Maximum pulse amplitude (12 volt system) (V)
Positive	75

CONDUCTED TRANSIENT EMISSIONS—Continued

Pulse polarity	Maximum pulse amplitude (12 volt system) (V)
Negative	−100

LIMITS FOR BROADBAND CONDUCTED DISTURBANCES

MHz	0.15–0.3		0.53–2.0		5.9–6.2		30–54		68–108	
	P	QP	P	QP	P	QP	P	QP	P	QP
a	93	80	79	66	65	52	65	52	49	36
b	80	67	76	63	62	49	62	49	56	43

a: power lines, limit in dB (uV).
b: control lines, limit in dB (uA).
P: peak detector.
QP: quasi-peak detector.

LIMITS FOR NARROWBAND CONDUCTED DISTURBANCES

MHz	0.15–0.3	0.53–2.0	5.9–6.2	30–54	68–87	76–108
a	70	50	45	40	30	36
b	60	50	45	40	40	46

a: power lines, limit in dB (uV).
b: control lines, limit in dB (uA).
limits by peak detection.

Test 15. Service Interval Display

Initialize the BAIID to begin the service interval period. After thirty (30) days, the BAIID must prominently indicate that it must be taken to a designated maintenance facility for maintenance and data downloads within 7 days or the vehicle will not start and the event will be logged. Over the course of the 7-day lockout countdown, the BAIID must prominently indicate that the BAIID is in need of service and the time remaining until ignition lockout. During this period, the vehicle may be started if other conditions for starting the vehicle are met. At the end of the 7-day lockout period, the BAIID must prominently indicate that the BAIID is in need of service and the vehicle must not start. Other tests (except Tests 14 and 16) may be performed during this 37-day period.

Test 16. Data Integrity and Format

Complete all other tests before performing Test 16. Download the data from the interlock data logger and compare it to the data recorded for each test. Disconnect, then reconnect the power to the interlock data logger. Download the data again and compare it to the first data download. No lost or corrupted data is allowed. Check the data format (i.e., date and time of event) to verify conformance with the sample format in Appendix D.

APPENDIX A—QUALITY ASSURANCE PLAN TEMPLATE

[Manufacturer name]

Quality Assurance Plan for

[Interlock name AND Model number]

[date]

This Quality Assurance Plan (QAP) and the operating instructions for the [Interlock name] provide step-by-step instructions for checking the accuracy of the calibration of a BAIID and the maintenance of the BAIID. (As noted in the Model Specifications, BAIIDs must hold calibration for at least 37 days (30 days + 7 day lockout countdown) and must prominently display the service interval and provide for a 7 day lockout countdown.)

1. Provide step-by-step instructions for checking the calibration of the BAIID. These instructions must include:

- Indication of the period of time that the BAIID can maintain calibration;
- Recommended calibrating unit(s) (listed on NHTSA's Conforming Products List of Calibrating Units for Breath Alcohol Testers) and instructions for using the calibrating unit(s);
- Breath alcohol concentration to be used in the calibration check(s): 0.02 g/dL BrAC;
- Agreement of the calibration check with the breath alcohol concentration of the calibrating unit: not greater than ± 0.005 BrAC
- Description of how to verify the accuracy of the BAIID reading of BrAC (e.g., from an instrument read out, printout, interlock data logger, etc.);
- Description of actions that must be taken if the BAIID fails the calibration check.

2. Provide instructions on downloading the data from the interlock data logger.

3. Provide instructions on how to maintain the BAIID (i.e., what must be examined during maintenance; any functions that require less frequent checks). Such instructions must detail any corrective action to be taken if the BAIID fails to perform as well as any events that would require a BAIID to be taken out of service and returned to the manufacturer.

4. Provide instructions on how to check for tampering.

5. Other information regarding quality assurance unique to this instrument, if any:

Contact information for the BAIID manufacturer regarding calibration and maintenance issues:

APPENDIX B—SAMPLE FORMAT FOR DOWNLOADED DATA FROM THE INTERLOCK DATA LOGGER

EXAMPLE 1—ACCEPTABLE START AND DRIVE CYCLE

Date	Time	Start attempts (engine activity)
4/21/07 ...	0951	start attempt.
		sample accepted.
		BrAC (alcohol absent, e.g., 0.000, 0.008).
		starter active.
	0952	engine on.
	0956	retest.
		sample accepted.
		BrAC (alcohol absent, e.g., 0.000, 0.008).

EXAMPLE 1—ACCEPTABLE START AND DRIVE CYCLE—Continued

Date	Time	Start attempts (engine activity)
	1032	engine off.

EXAMPLE 2—ACCEPTABLE START BUT FAIL ROLLING RE-START

Date	Time	Start attempts (engine activity)
4/22/07 ...	2316	start attempt.
		sample accepted.
		BrAC (alcohol absent, e.g., 0.008).
		starter active.
	2317	engine on.
	2319	retest.
		BrAC (alcohol present, e.g., 0.025).
		warning given.
4/23/07 ...	0047	engine off.

EXAMPLE 3—PUSH START

Date	Time	Start attempts (engine activity)
4/23/07 ...	2054	ignition keyed.
		warning given.
		starter not active.
	2055	engine on.
		warning given.
	2120	engine off.

EXAMPLE 4—START ATTEMPTED BUT ALCOHOL DETECTED. RETRY

Date	Time	Start attempts (engine activity)
4/21/07 ...	1652	start attempt.
		sample accepted.
		BrAC (alcohol present, e.g., 0.030).

EXAMPLE 4—START ATTEMPTED BUT ALCOHOL DETECTED. RETRY—Continued

Date	Time	Start attempts (engine activity)
	1653	warning given.
	1656	start attempt.
		sample accepted.
		BrAC (alcohol absent, e.g., 0.015).
		starter active.
	1657	engine on.
	1702	retest.
		sample accepted.
		BrAC (alcohol absent, e.g., 0.010).
	1850	engine off.

EXAMPLE 5—START ATTEMPTED USING FILTERED SAMPLE. RETRY

Date	Time	Start attempts (engine activity)
4/15/07 ...	2016	start attempt.
		low temp.
		warning given.
	2205	start attempt.
		sample accepted.
		BrAC (alcohol absent, 0.000).
		starter active.
	2206	engine on.
	2352	engine off.

EXAMPLE 6—CALIBRATION CHECK

Date	Time	Start attempts (engine activity)
4/28/07 ...	0900	start attempt.
		sample accepted.
		BrAC (alcohol absent, 0.000 or 0.008).
		starter active.
	0903	engine on.
	0926	retest.

EXAMPLE 6—CALIBRATION CHECK—Continued

Date	Time	Start attempts (engine activity)
		sample accepted.
		BrAC (alcohol absent, 0.000 or 0.008).
	1032	engine on.
	1045	Calibration check.

Issued on: May 3, 2013.

Jeffrey Michael,

Associate Administrator for the Office of Research and Program Development National Highway Traffic Safety Administration.

[FR Doc. 2013–10940 Filed 5–7–13; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Quarterly Publication of Individuals, Who Have Chosen To Expatriate

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: This notice is provided in accordance with IRC section 6039G of the Health Insurance Portability and Accountability Act (HIPPA) of 1996, as amended. This listing contains the name of each individual losing United States citizenship (within the meaning of section 877(a) or 877A) with respect to whom the Secretary received information during the quarter ending March 31, 2013. For purposes of this listing, long-term residents, as defined in section 877(e)(2), are treated as if they were citizens of the United States who lost citizenship.

LAST NAME	FIRST NAME	MIDDLE NAME/INITIALS
ABDULAZIZ ABDULLAH AL SAUD	SADEEN	
ABRAM	ISAAC	ZIKO
ADAMS	STANLEY	PHILLIP
ADRIAN	SHEILA	MAY
AHOUR	RAMIN	
AKRE	JAMES	EUGENE
AKRE	PIA	SOPHIE
AL–JALLAL	ZIYAD	ABDULAZIZ
AL–KAZEMI	MAY	FAISAL
ALOMRAN	ABDULAZIZ	
AL–RUMAIM	TAREK	
AL–SABAH	BIBI	MURBARAK
AL–SABAH	YASMINE	MUBARAK
AMARAL	DAVID	MICHAEL
AMMANN	HOPE	TRUDY
ANDO	YUKI	
APEL	EVA	NOELLE
ARIAS	MADELAINE	ANTONIA
AROSEMENA III	ROGELIO	AUGUSTO
ASKAR	EMAD	A
ASTROW	ANDRE	IGOR

LAST NAME	FIRST NAME	MIDDLE NAME/INITIALS
BABINEAU	MARIE	BRENDA
BAILLIE	IAIN	CAMERON
BAILLIE	JOAN	MARY CHRISTINE
BAKER	EARL	
BALAZ	MARKUS	CHRISTIAN
BALDWIN	SARAH	ANNA GERRING
BANG	HEESEUNG	
BARRAZA	SANTIAGO	E
BARTEL–MOUFANG	DIANA	
BATTIG	RAINER	KARL
BAUMANN	MARTIN	PETER
BAUMBERGER	ALEXANDRA	SUSAN
BAUMBERGER	JACQUELINE	SUE
BAUR	ROBERT	GEORGE
BAYER	JOHN	JAMES
BEARE	PETER	WILLIAM RICHARD
BEERCROFT	DIANE	DERBY
BENISTANT	KELLY	MARIE
BENNETT	JESSICA	ANN MARY
BENTLEY	MARK	EDWARD
BERNING	HANS	JOACHIM
BERRY	AURELIE	ELENA
BERRY	MARINA	SULZBERGER
BHANG	SUN	HEE
BINDING	GARRET	SHEEHY
BLAETTLER	IRIS	CAROL
BLEAU	SYLVAIN	
BLOOMFIELD	RICHARD	JOHN
BLUNDEN	KATHERINE	ANN
BLUNT	ALICE	GENEVIEVE
BONAERT DE LAUBESPIN	ELEONORE	M.J.M.
BONNE	ALEXANDRA	
BOODY	MIRIAM	JANE
BOSCHERT	CATHERINE	ANNE
BOSCHERT	CYRIL	ANTHONY
BOYD	SONYA	YOLANDA
BRACK	HANS	PETER
BRAMSTEDT	KATRINA	ANDREA
BRANDENBERGER	VERENA	CAROLINE
BRANDT	CHRISTOPHER	ANDRE
BREITENMOSER	ERICH	
BREZINA	KAREN	JANE
BRIGGS	CAROL	ELIZABETH
BROADWAY	AARON	DUKE
BRUEGGEMANN	IRMGARD	ELISABETH
BRUEGGEMANN	KONRAD	
BRUNOT	NANCY	VARENNE
BUCH	MARION	SUSAN
BUCHWALDER	RENE	WERNER
BUERGI–SAVILLE	MARY	ELIZABETH
BUHLMANN	GABRIELA	ANNA
BUNTING	ALAN	
BUNTING	LINDA	CATHERINE
BURNSIDE–NORMAN	JANET	
BUSE	CHARLES	TWEEDT
CAIN	PATRICK	ELIOT MACAULAY
CALAME	THIERRY	JAMES
CALEDON	WENDY	CATHERINE
CALGHER	MARTA	
CALLAHAN	PAUL	RYAN
CAMPBELL	BRYCE	ROBERT
CANTINI	UGO	PAUL
CANTINI–FISHER	LAURA	
CARRELL	ELIZABETH	ANN
CASADEI–MARMET	DANIELLE	BEATRICE
CASEY	JANE	ANNE
CAVEGN	BARBARA	ELISABETH
CERQUEIRA	JOHN	DA SILVA
CHAMEIDES	ANDRE	MAXIMILIAN
CHAMEIDES	LILLIAN	JOAN
CHANG	DOUG	SOON
CHANG	JACLYN	
CHAPPELL	DALE	BRIAN
CHEE	MARY	KIASUANG

LAST NAME	FIRST NAME	MIDDLE NAME/INITIALS
CHEN	HSIAO	HUNG NANCY
CHENG	JESSICA	ANNE
CHEUNG	ALLISON	
CHIANG	HUIHUA	KENNY
CHIN	HOLMAN	
CHO	KYUNG	JA
CHOI	UK	JIN
CHRIQUI	GENEVIEVE	MARIE
CHRIQUI	JOSEPJ	
CHUA	KATHLEEN	XIU ZHEN
CIESLAK–VAN DER KLINK	NADIA	
CLAGETT	DENNIS	MARSHALL
CLARK	KEVIN	ALEXANDER
CLIFF	CHRISTOPHER	STEVEN
COHOON	KERRY	BETH
COLLINS	RONALD	CHARLES
COLLINS	SEAN	DAMIAN
CONSTANTINE	CHARLES	THOMAS
COOK	NEIL	PATRICK
COSENTINO	LILIANA	
COSENTINO	MANUELA	
COUPER	JESSICA	ELAINE
CROWDER	MARCUS	JOHN
CULVERWELL	ALOSON	MURIEL
CURJEL	KAREN	CECILLE
CURRALL	SUSAN	MAYNE
CURRAT	VIRGINIA	ELIZABETH
DAHER	MICHAEL	GHALEB
DANENZA	ANDREW	ADNAN
DANIEL	EMILY	LOUISE
DANUBIO	SUSAN	KATHARINA
DARDIER	JEAN–MARC	HENRI
DARMON	GREGORY	PATRICK
DARMON	MATT	MOORE
DAS	SANJOY	
DAVIDSON	ALAN	RICHARD
DE LAMBILLY	NATHALIE	MARIE
DE MARCO	DIANA	MARY
DE MEESTER–DE HEYNDONCK	ORLANDE	CHRISTIANE
DE MERODE	CHRISTOPHER	LAWRENCE
DE MORTANGES	CHARLES	F W PAHUD
DE PAREDES	SUSANA	GARCIA
DEALY	JOHN	MICHAEL
DECKER	BARBARA	
DEDEYSTERE	CAROLINE	IRENE
DELESIE	KATRIEN	MARIE–PAULE A.
DESPLAND	OLIVIER	PIERRE
DEWARRAT	SYLVIANE	COSETTE
D'HULSTER	ANNA–MARIA	LOUISA ANDREA
DIAB	AMIN	BARAKAT
DOAN	KARIN	ANNE
DOAN	RICHARD	JOSEPH
DOMIATI	SAMATHA	ELIZABETH
DONNER	RICHARD	JOHN
DONZ	ISALINE	
DOREY	ROBERT	
DOS SANTOS	JULIA	LEAL GOMES
DOURGE	PAUL	LEON
DROULERS	ALEXANDER	CHARLES
du PARC LOCMARIA	AGNES	MARIE–GABRIELLE
DUHANEY	LADNER	SEYMOUR
DUNCAN	VALLE	ROZIER
DUNCAN, JR.	WILLIAM	GLENN
DUNHAM	JOSEPH	EDWARD
DURALL	DANIEL	MARTIN
DUTOIT	BERTRAND	MICHEL
EGGIMANN–STEINER	PAULA	CHRISTINE
EISENHUT	YANNIS	FABIAN
ELDER	LORNE	EVERETT
ELGIN–DUNLOP	MIRANDA	GRACE
ELMIGER	BEAT	ANTON
ELMIGER	JUERG	RAINER
ELSER	MITCHELL	JON
EMERSON	CLAUDETTE	ANN

LAST NAME	FIRST NAME	MIDDLE NAME/INITIALS
ENDER	LAURA	
ENDER	OLINDA	MARIA CAVEGN
ENGLISH	CHRISTEN	HOPE
ENGLISH	DANIEL	
ENGLISH	JOEL	ANDREW
ERISMANN	CATHERINE	
ERNST–CHENG	LINNA	
ERWIN	VIRGINIA	JEAN
ESTRYN	GEORGE	VICTOR
EVELYN JR	GEORGE	ELBERT
EVERSFIELD	SARAH	
FABER	REBECCA	
FAN	RONALD	JIU NING
FANG	CHIH–SHANG	
FARJAM	SOUSSAN	
FARNER	ISABELLA	ELIZABETH
FELLER	ANISSA	JAMILA
FENDRICK	JOYCE	ELLEN
FENG	TONY	
FERRIN	DAVID	ALAN
FIGUEROA	MONICA	RENATA DOCHERTY
FINK	MICHAEL	ALLEN
FISCHER	ISABELLE	CHANTAL
FISCHER	NELLY	TEMOCHE
FITZ–THOMMEN	KARIN	RUTH
FLETCHER	MARGARET	JANE
FLOWERS, JR.	ROGER	WILLIAM
FOLKOFF	AARON	ZACHARY
FONTANA	THERESE	
FORD	BRIAN	WILLIAM
FORGIE	HUGH	DOUGLAS
FORSYTHE	SARA	
FOX	KENNETH	R
FOX	REBECCA	JANE
FRAZIER	CATHERINE	ARLENE
FRAZIER	JERRY	WADE
FREEMAN	BRET	R.
FREIHA	HASSIBA	BASSAM
FREMMERSVIK	BETTY	SOPHIE
FREY	HAROLD	BORIS
FRISCHKNECHT	DOMINIC	PETER
FUGLISTER	THOMAS	
FULLMER	MICHAEL	KEITH
GALBRAITH	SARA	GRAYSON
GARRIGUS	TODD	LAMONT
GELLERT	ELIZABETH	CLARIDGE
GERARD	ROBERT	EDWARD
GERBER	RICHARD	
GERBER	SUSAN	CHARLOTTE
GERMOND	ANJA	CHRISTINE
GERSBACH	KRISTINA	ELISABETH
GETTY	ISABEL	CHRISTINA EMANUELLE
GLESTI	THOMAS	STEVEN
GOLDSTEIN	ABRAHAM	R.
GOLDSTEIN	DAVID	ZRUBAVEL
GOMEZ	ISABELLE	CHRISTINE
GRANT	JASON	ANDREW
GRAY	STEPHEN	JOSEPH
GREEN	EMILY	ANAIS HUGHES
GREEN	PATRICIA	ANN
GREEN	PATRICK	RICHEY
GREENWOOD	ROBERT	ARTHUR
GRIGORIEV	DENIS	NIKOLAEVICH
GROETSCH	ANDREA	EMILLIE
GRUMAN	CAMILLE	CLAIRE
GRUMMENACKER	REGINA	ANNA
GUGGITZ	LYDIA	MARIA
HAARER	JOHANNES	PETER
HABLUTZEL	MARIA	GUADALUPE
HAENGGI–SCHAUFELBERGER	VIOLETTE	MARIANNE
HAENNI	SIMON	FRANCIS
HAGGLOF	ANDREA	CHRISTINA
HAGGLOF	CLAES	RICHARD
HAGMANN	BEATRICE	

LAST NAME	FIRST NAME	MIDDLE NAME/INITIALS
HAGMANN	WALTER	
HAKOZAKI	SEIJI	
HALEY–UHLMANN	ALICE	
HALL	KATRINA	FAVELL
HAMILTON	WILLIAM	NEILSON
HAN	DANIEL	SEUNGCHUL
HAN	STEVEN	DONGHEE
HAND	VESSILA	ZHIVKOVA
HARLESS	RUSSELL	BRISTOW
HARRIS	TATSUMI	MICHAEL
HARTMANN	RUDOLPH	
HARTMANN	SUSANNE	BARBARA
HATHAWAY	JANET	K
HAUPTLI	DIANE	MARIE
HAY	KATHERINE	MARIE
HEBRON	VERA	
HEIM	JULIA	
HEIM	MARC	ALAIN
HEMMER	DORA	
HENNESSY	STEPHEN	ERNST
HENSCHKE	LELAND	
HERRERA	PAOLA	
HERRMANN	CELINE	
HERRMANN	HENRIK	
HERTACH	KAARIN	STEPHANIE
HEUSSER	MICHAEL	CHRISTOPH
HEYMANS	PHILIPPE	JACQUES
HEYNEN	SEBASTIAN	CHRISTIAN
HILL	MARSHA	ANN
HILL	SCOTT	GREGORY
HIRAI	LISA	
HIRSHBIEN	DROR	
HOEPKER	ELMER	CHRIST
HOEPKER	WALTRAUD	MARIA
HOFER	CATHERINE	LOUISE
HOFER REYES AGUIRRE	STEFANIE	CHRISTIN
HOLLAND	JEFFREY	SCOTT
HOLLIGER	BEATRICE	CHARLOTTE
HOLTON	ALBERT	JOHN
HOMSI	SUHAIL	KAMEL
HONG	TEDDY	P
HOPPE	MICHAEL	
HOPPER	JAMES	RICHARD
HOSOTSUJI	KENSAKU	
HROVAT	ROBERT	KLEMEN
HSU	VICTORIA	
HUDOVERNIK	ISABELLE	MARIE–CHRISTINE
HUGES–GREEN	CHRISTOPHER	GEORGE
HUGHES	LEH	HEAN
HUNGERBUHLER	VANESSA	
HUYGEN	KIM	
HYDE	JESSICA	LYNN BAUMGARTEN
HYNDMAN	ANDREW	SCOTT
IDILBY	KARIM	ZIAD
IMAMOGLU	ATAC	
IN	YUNICE	YUN
INGRAM	JAMES	RONALD JOHN
INOUYE	NAOMI	KENNETH
ISELIN	WILLIAM	ALEX
ISOARD	MARIE	TUROLLA
JABR	WISSAM	F.
JAWA	JAMAL	AHMED
JEEVANJEE	SALMA	
JOHNSON	CRYSTAL	DENISE
JOHNSON	JASON	BOB
JONES	ALEXANDER	VAJSOVA
JOST–LEDER	JOANNA	ELIZABETH
JOWETT	KIERSTEN	JULIA
JUD	MARLISE	NATALIE
JUNG	KOOYUL	
KAMPMANN	VERONIQUE	
KANG	DONG	YOON
KAO	TIMOTHY	DANIEL
KARZAI	MAHMOOD	

LAST NAME	FIRST NAME	MIDDLE NAME/INITIALS
KAUFMANN	CHRISTINE	ANITA
KAUFMANN	FELIX	HANS
KAUL	AJAI	MOHAN
KAWATE	TAKASHI	
KEEGAN	CHRISTOPHER	JOHN
KEELER	ELISABETH	A
KEELER	SAMUEL	JOSEPH
KEELER	TODD	BYRON
KEENAN	KELLY	ANNE
KELSALL	KEITH	PHILIP
KENNEDY	JOSEPH	PAUL
KERKER	KATTRIN	ANDREA
KERKER	STEPHANIE	CHRISTINA
KERNLAND	MARTIN	EGIL
KERR	SUSAN	LEE POAD
KESSLER	PHILIPPE	NICOLAS
KETTANEH–MEJANES	ISHTAR	THERESE
KIM	YOUNG	OK
KIMCHE	DEGANIT	MEIRA
KIM–KWON	MYUNG	JA
KINGDON–GRUENWALD	ELIZABETH	
KISH	ALADAR	FRANK
KITTREDGE	FRANK	HOLMES
KLADDE	JOHN	RICHARD
KLEINER	KAREN	ELISABETH
KLESCH	A. GARY	EDWARD
KLESCH	ANITA	MAE
KO	MICHELE	TIEN–WAH
KOBLET	HANSBEAT	BEAT
KOENITZER	KATHERINE	W
KOERNER	KARL	GREGORY
KOH	MONIQUE	WEILING
KRAAN	HERMINA	CORNELIA
KROLL	DETLEF	MARTIN
KUHNS	MICHAEL	RICHARD
KUNNASAGARAN	NIRASHA	
KUNZ	DANIEL	ANDREAS
KUO	RAYMOND	CHYNG JEN
LACK	STEPHEN	GEOFFREY
LAM	SCHEHERAZADE	HERA
LANDOLT CASPAR	HEDY	AGNES PATRICIA
LANG	NIELS	CHRISTIAN
LANGFORD	KENNETH	ROYSTON
LAPAN	DIANNE	MARIE
LARGE	JUDITH	ANN
LAWRENCE	CLARE	SEAN
LAWSON	ANITA	
LAWSON	THOMAS	OLIVER
LEE	DAVID	MINZAE
LEE	GRACE	HYUNJU
LEE	HYUK	
LEE	KEVIN	
LEHMANN	ANDREAS	PETER
LEMMIN	NICOLAS	JOHN
LEUBA	NICOLAS	CHRISTIAN
LEUENBERGER–REINHART	CHRISTINE	CECILIA
LEVENE	LOUIS	STEVEN
LEVERRIER	MARIE	HELENE
LIAO	SHU–CHIN	
LIEU	SUUN–CHEN	
LIM	MELISSA	CHENG–YONG
LINIGER–KERLAND	MARK	ANDREA
LIPS–RAUBER	CHRISTINA	ANN ELIZABETH
LIVINGSTON	MARK	PHILLIP
LLIFFE	DEBORAH	MARCI
LLOYD	MARGARET	AU
LOCKE–TECKEMEIER	LORETTA	ULLRICH
LOCKE–TECKMEIER	LORETTA	U.
LONG	CHRISTINE	
LONGLOTT	JOHN	ALFRED
LOUVET	VERONIQUE	F
LOW	ATHENA	HWEE–LENG
LOY	SEBASTIAN	JEFFREY
LYSTER	RUSSELL	JOHN

LAST NAME	FIRST NAME	MIDDLE NAME/INITIALS
MA	CUI	QUN
MADI	TALA	SHEHABEDDIN
MADURO	ALFREDO	LUIS
MADURO	PEGGY	CECILIA
MALONEY JR,	RICHARD	DAVID
MANNING	NATHAN	MERLYN
MANTEI	NED	ARTHUR
MANTEI	THOMAS	
MANTEI	VANESSA	ANNA
MARCOTTE	LESLIE	AGNES
MARKHAM	AMANDA	JULIET
MARLAND	CHRISTOPHER	
MARTIN	DEBORAH	
MASTERMAN	KENNETH	GEORGE
MC ADAM	KRISTIN	LYNN
MCCONNELL	PETER	CHARLES
MCFADDEN	NICOLAS	GALLICE
MCKENZIE	ALASTAIR	JAMES
MCMAHON	STEPHEN	
McMEEKIN	SAN	TERENCE
MEAD	ANJALEE	DEVENDRA
MEAGHER	CINDY	DAWN
MEEHAN	MATTHEW	JOSEPH
MEIER	MARCEL	HUGO
MENET–CIESLAK	AHMIE	IRENE
MENTEN	JENNIFER	
MESSER	ANJA	
METAXAS	KIMBERLY	EVELYN
METZGER	MARGARET	SHEILA
METZLER	CHANTAL	MARIE
MEZZADRI	URS	
MICHAELS	ANDREW	
MICHEL	JUDY	DIANE
MILLS	ANITA	LOUISE
MIOZZARI	HERMES	
MONDADORI	FILIPPO	
MORRICE	MELINDA	ISABEL ARIAS
MORRICE JR	FRANK	
MOSES	JUAN	RAUL ROUX
MOSSERI–MARLIO	CHARLES	ALEXANDRE
MUELLER	GABRIELE	SUSANNE
MUELLER	JANINE	DOROTHEA
MULLER	NICOLAS	JOHANNES
MUSTAFAWI	BADER	AHAMID
MUZYKA	DMITRY	
NAFZIGER	DONALD	WAYNE
NEAL	JANE	VALERIE
NEITHARDT–HOWARD	HELEN	CLAIR
NESTERENKO	MICHAEL	DOMINIQUE
NORRIS	STEPHEN	ROBERT
NORTON	JUDITH	ANN
NUSSBAUMER–DOLEZAL	BLANCA	IRENE
OBSCHLAGER	KEVIN	FRED
OERTILI	JOHANN	JAKOB
OERTLI	REGULA	EMMA
OHANNESIAN	PAUL	B.
OLSON	LAURA	LEE
ORTMANS	OSCAR	ARCHIBALD GUY
OSTBERG	NILS	ERIC
OSTIER	GREGORY	ALEXANDRE
OWEN–RICHER	GWEN	
PARK	HWI	JUNG
PARK	JAIOOK	
PARK	SIEHYUN	
PARK	YONG	JIN
PARSONS JR	THOMAS	HENRY
PELIZZON	MARINA	SYLVIA
PELUSO	FREDERICK	JOSEPH
PENG	SHI	FEN
PERRY	RANDALL	STEWART
PFANDER	MARC	THOMAS
PHILIPPE	ANNE	JEANNE MADELEINE
PHILIPPE	MICHAEL	ROGER
PICHLER	LUCAS	TOBIAS

LAST NAME	FIRST NAME	MIDDLE NAME/INITIALS
PIM	SALLY	ELIZABETH
PINTER	MARGARET	ETHEL
PIPES	JON	ERIC
PITTALUGA	MARCELLA	JANE
PLOTNIKOFF	JOYCE	EVELYN
POK	DAPHNE	YU–MEI
POON	DEREK	KA–WEI
POPOVICH	JAOHN	PAUL
POWELL	ROY	MCNEAL
PRAXMARER	MANUELA	EVELYN
PRINZHORN	THOMAS	CORD
PROFFITT	DANIEL	WILLIAM
PU	MARGARET	
PURY	ISABELLE	
PUSATERI	SALVATORE	JOSEPH
QUINN	ALEXANDRA	SARAH ELLICOTT
RAJWITSCHER	IRINA	
RAMSTEIN	LISA	A.
RASHTI	CAMERON	ANTHONY
RAYNER	TESSA	JOY
REBITZER	GERALD	ALEXANDER
REDDISH	LESLEY	GREER
REDNER	RON	CHAIM
RELYEA	WALTER	BYRON
REUBEN	DEBRA	
REUSSER–ZONDLER	BIRGIT	
REVERDIN	CHRISTOP	ALEXANDRE
RICHARDS	MYEONG	CHA
RICHARDSON	SUSAN	JANE
RIESEN–GRASSLER	MONIQUE	ANNE
RINGIER	ADINA	SOPHIE
RINGIER	DAVINA	LILLY
ROBINSON–YAKELEY	STEPHEN	
ROCHAT	CHRISTIANE	
RODIN	LENA	IRENE
RODIN–MEDINA	TANIA	ELIONORA
ROHNER	MARLIES	ARNETTE
ROOT	FRANCIS	JEROME
RUPP	STEPHAN	
RUSSELL–SIENESI	JANICE	LUCY
RYAN	STEPHEN	ALEXANDER
SABBAGH	RAJA	NEMEH
SADEGHI	SOGHRA	MADELEINE
SADIK	ELSHEREEF	ZEID HARITH
SAEMANN	LILIAN	ALICE
SAI	ABDUL	RAHMAN MOHAMMED
SAKALLAH	SUZIE	T.
SALATHE	MARK	WILLIAM
SALATHE	MONICA	JACQUELINE
SALEM	SALEM	A
SALTER	WILLIAM	DAVID
SAMIDA	RAINER	JOHN
SANDOZ	MARIA	ELENA JACQUELINE
SARAFA	ANTHONY	ALAN
SAVAGE	LESLIE	ANN
SAVAGE	SEAN	ANDREW
SCHAER	ESTHER	DORA
SCHAERER	KAREN	
SCHAERER	MICHAEL	
SCHAERER	NICHOLAS	
SCHEU	KATHRIN	DANIELA
SCHILD	BARBARA	
SCHMID	ANDREW	
SCHMIDT	KIM	MELANIE
SCHMITH	SCOTT	CHARLES
SCHMOCKER	ANDREAS	STEVEN
SCHNELLMANN	KATHRIN	
SCHOLEFIELD	JACQUELINE	ANNE
SCHRAMM	GERHARD	
SCHREDER	CYRILLE	ALBERT–DENIS
SCHUBERT	MONIKA	NANCY
SCHUERCH	CARMEN	FULVIA KUMMER
SCHWARTZ	TAMARA	
SCHWEIZER	ANDREA	SUSAN

LAST NAME	FIRST NAME	MIDDLE NAME/INITIALS
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SEEHOLZER	MONICA	
SELVIDGE	DEREK	BRET
SEO	CHONG	AE
SHARPE	DAVID	RICHARD JAMES
SHEDIAC	RICHARD	CAESAR
SHEN	MARGARET	YIN MAN
SHIMODA	JODY	ANN
SILVERSTEIN	A	JAY
SIMON	DOUGLAS	NORMAN
SIMONI	ANNE	WINKLER
SIMONI	CARLO	ALBERTO
SLEE	ALEXANDER	WILLIAM WOLF
SMITH	ANNETTE	GABRIELLE
SMITH	GEMMA	HARRIET ROSAY
SMITH	HOSANNA	ISRAEL
SMITH	STEVEN	JOHN
SNG	JOSHUA	JIN WEI
SOLTANIEH	SHABNAM	
SONG	SUNG–HEE	
SOON	DOMINIC	CHEE
SPADOLA	LUCA	ANTONIO
SPAHR	LAURENT	FRANCOIS
SPERB	FERDINAND	
SPYRIS–METAXAS	ANDREW	PHILLIP
ST. JOHNSTON	FREDERICK	IAN
STAEHELIN	NANCY	ANN
STAHEL	MICHELLE	DENISE
STANFORD	JUDITYH	ANNE
STAUFER	KATRIN	LISA
STEHLIN	MARC	PIERRE
STEINEGGER	ELFRIEDE	
STEINEGGER	JUERG	M.
STEINER	TESSA	ANN
STERLING	RICHARD	MORRIS
STIEFEL	NIKLAUS	GEORG
STOCKLI	EDITH	CATHERINE
STOLLHOF	NORMAN	MARCUS
STOLZ	MARK	EDWARD
STRICKER	MARTIN	ERICH
STROTMANN	CARROL	PATRICIA
STUBER	GABRIELE	BEATRICE
STUCKY	ERIKA	DORIS
STUDER	ANTON	ALOIS
SULC	DAVID	THEODORE
SULZER	MARAGARET	ELIZABETH
SUN	DIANA	XIAOXIN AI
SUNDBERG	NANCY	JOHANNE
SUTTON	JANET	RISA
SZURAN	CHRISTINE	ELISABETH
TAKEMURA	SHUMA	
TAN	ANNA	GUEK YONG
TAN	JUI HANG	BEJAMIN
TAN	LISA	MARIE
TANG	XIN–YI	DANIEL
TASILLO–HIRT	ANN	M.
TAYLOR	CURTIS	GORDON
TEITLER	NURIA	JANINE
THOMANN	KATHLEEN	MILLY
THOMAS	SILVIA	MAGDALENA
THOMAS	STEPHEN	SIDNEY
THOMMEN	DOROTHY	HELEN
THOMPSON, JR.	BARRY	DELTON
THURNHERR	THOMAS	BRUNO
TING	SHERYL	HSIEN–JU
TIRMAN	GEOFFREY (JEFFREY)	JOHN
TISSOT–DIT–SANFIN	BARBARA	ALICE
TOMPKIN	CHRISTINA	SIGG
TOMPKIN	WAYNE	ROBERT
TORGENSON	PAUL	ROBERT
TOROK	JAMES	ANDREW
TORPHY	MICHAEL	DAVID
TROST	MINNA	ROSWITHA
TSAI	ALICE	FENG–FANG

LAST NAME	FIRST NAME	MIDDLE NAME/INITIALS
TSCHURTSCHENTHALER	PAUL	MATTHEW
TSOUVELEKAKIS	DEMETROIS	
TUQAN	SALMA	USAMA
TUQAN	TAREK	USAMA
TYNAN	MYRA	CLAIRE
TYTGADT	JEAN–PHILIPPE	LUCIEN
VAN DER LOOS	MARYSA	CHRISTINE
VAN DRIEM	GEORGE	LOUIS
VAN HERTSEN	ISABELLE	MARIE
VANDEN–BERGHE	HELEN	ANN
VERNER	JAMES	AUGUSTINE
VOGEL	CHRISTIAN	MARTIN
VOGT–MUEHLEMANN	SALLY	MADELENE
VOLLENWEIDER–ROTEN	SONJA	IRENE
VON GEMMINGEN–HORNBERG	MICHAEL	PLEIKARD
WAGNER	WOLFGANG	KARL
WALLACE	ELISABETH	
WANDER	FRANCOISE	MARIE MAGDELEINE
WANG	AI–LI	
WANG	AI–LIN	
WANG	ANDREW	RUI WEN
WANG	DENNIS	
WANG	LILI	
WATTIAUX	JACK	
WATTS	UTE	KATE
WEBER	CAROLINA	MARY
WELLS	MADELINE	
WENTZ III	DANIEL	STAIR
WESTERN	ALFRED	WARD
WHITE	DAVID	ANTHONY
WIDMER–NOETZLI	FRANZISKA	MARIA
WIGGENHAUSER	MARTIN	ANDRE
WILLERS	STANLEY	
WINDEMUTH	EDITH	KATHREEN
WINNINGTON	EDWARD	ALAN
WIRTHNER	MONA	MARGUERITE
WONG	ADA	YUK NG
WONG	GEORGE	KA KUI
WONG	JOELYNN	JAILIN
WOO	STEPHEN	HENG–CHE
WU	JOHN	JIONG
WU	QU	OU
WUETHRICH	MARTINA	HELEN
WULLSCHLEGER–LUDLOW	SYLVIA	JEANNE
WURMBOECK	ALICE	VERENA
WYMAN	SUZANNE	ACCOSTA
XIE	ZAN	XIANG
YADIGAROGLU	CHARRIS	GEORGE
YANSOUNI	LAURENCE	
YASSIN	SAMMY	AKRAM
YATES–DAVIS	MARY	
YAU	ROLAND	CHE WAI
YEATES	EUNICE	MARY
YIK	BONNIE	KA MING
YIM	ELIZABETH	
YIM	JON	BENNI
YOUNG	CHRISTA	ELIZABETH ETIENNE
YUJUICO	GABRIELLE	FRANCESCA
ZARDA–HESS	ANNATINA	
ZEITMAN	ALLEN	MICHAEL
ZEITMAN	LIKAS	JOHANNES
ZIELINSKI	CAMILLA	CAROL
ZOESCH	RICHARD	WILLIAM
ZURBUCHEN	RICHARD	WALTER
ZURFLUH	MARGRIT	JEAN
ZWACK de WAHL	ISABELLA	VERONIKA

Dated: April 19, 2013.

Ann V. Gaudelli,

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 412

Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2014; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1448–P]

RIN 0938–AR66

Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2014

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the prospective payment rates for inpatient rehabilitation facilities (IRFs) for federal fiscal year (FY) 2014 (for discharges occurring on or after October 1, 2013 and on or before September 30, 2014) as required by the statute. We are also proposing to revise the list of diagnosis codes that are used to determine presumptive compliance under the ''60 percent rule,'' update the IRF facility-level adjustment factors, revise sections of the Inpatient Rehabilitation Facility-Patient Assessment Instrument, revise requirements for acute care hospitals that have IRF units, clarify the IRF regulation text regarding limitation of review, update references to previously changed sections in the regulations text, and revise and update quality measures and reporting requirements under the IRF quality reporting program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 1, 2013.

ADDRESSES: In commenting, please refer to file code CMS–1448–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1448–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1448–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments only to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Gwendolyn Johnson, (410)786–6954, for general information about the proposed rule. Caroline Gallaher, (410) 786–8705, for information about the quality reporting program. Susanne Seagrave, (410) 786–0044 or Kadie Thomas, (410) 786–0468, for information about the proposed payment policies and the proposed payment rates.

SUPPLEMENTARY INFORMATION: The IRF PPS Addenda along with other supporting documents and tables referenced in this proposed rule are available through the Internet on the CMS Web site at *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/.*

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Executive Summary

A. Purpose

This proposed rule updates the payment rates for inpatient rehabilitation facilities (IRFs) for federal fiscal year (FY) 2014 (for discharges occurring on or after October 1, 2013 and on or before September 30, 2014) 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 prospective payment system's (PPS) case-mix groups and a description of the methodology and data used in computing the prospective payment rates for that fiscal year.

B. Summary of Major Provisions

In this proposed rule, we use the methods described in the FY 2013 IRF PPS notice (77 FR 44618) to update the Federal prospective payment rates for FY 2014 using updated FY 2012 IRF claims and the most recent available IRF cost report data. We are also proposing to revise the list of diagnosis codes that are used to determine presumptive compliance under the ''60 percent rule,'' update the IRF facility-level adjustment factors using an enhanced estimation methodology, revise sections of the Inpatient Rehabilitation Facility-Patient Assessment Instrument, revise requirements for acute care hospitals that have IRF units, clarify the IRF regulation text regarding limitation of review, update references to previously changed sections in the regulations text, and revise and update quality measures

and reporting requirements under the IRF quality reporting program.

C. Summary of Costs, Benefits and Transfers

Provision description	Total transfers
FY 2014 IRF PPS payment rate update	The overall economic impact of this proposed rule is an estimated $150 million in increased payments from the Federal government to IRFs during FY 2014.

To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

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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 (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 IRF's 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 IRF 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. The Web site is: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/index.html?redirect=/InpatientRehabFacPPS/* and 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 proposed 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, and 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 proposed 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) 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, November 16, 2010) 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 proposed 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 regulations 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).

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 proposed productivity adjustment for FY 2014 is discussed in section V.A. of this proposed rule. Section 3401(d) of the Affordable Care Act requires an additional 0.3 percentage point adjustment to the IRF increase factor for FY 2014, as discussed in section V.A. of this proposed 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 new 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) will require 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). Under section 1886(j)(7)(D)(iii) of the Act, the

Secretary is required to publish the measures that will be used in FY 2014 no later than October 1, 2012.

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 Inpatient Rehabilitation Facility-Patient Assessment Instrument (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-digit CMG number. The first digit is an alpha-character that indicates the comorbidity tier. The last 4 digits 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.hhs.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-digit CMG number and sends it to the appropriate Medicare fiscal intermediary (FI) or 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 Medicare contractor. 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, November 25, 2005). CMS 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 healthcare 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 Medicare FI or 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 this proposed rule, we are proposing to update the IRF Federal prospective payment rates, to revise the list of eligible International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM) diagnosis codes that are eligible under the ''60 percent rule,'' to update the IRF facility-level adjustment factors, to revise the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI), to revise requirements for acute care hospitals that have IRF units, clarify the IRF regulation text regarding limitation of review, and to revise and update quality measures and reporting requirements under the quality reporting program for IRFs. We are also proposing to revise existing regulations text for the purpose of updating and providing greater clarity. These proposals are as follows:

A. Proposed Updates to the IRF Federal Prospective Payment Rates for Federal Fiscal Year (FY) 2014

The proposed updates to the IRF federal prospective payment rates for FY 2014 are as follows:

- Update the FY 2014 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 this proposed rule.
- Update the FY 2014 IRF PPS facility-level adjustment factors, using the most current and complete Medicare claims and cost report data with an enhanced estimation methodology, in a budget neutral manner, as discussed in section IV. of this proposed rule.
- Update the FY 2014 IRF PPS payment rates by the proposed market basket increase factor, based upon the most current data available, with a 0.3 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iii) 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 this proposed rule.

- Discuss the Secretary's Proposed Recommendation for updating IRF PPS payments for FY 2014, in accordance with the statutory requirements, as described in section V. of this proposed rule.
- Update the FY 2014 IRF PPS payment rates by the FY 2014 wage index and the labor-related share in a budget neutral manner, as discussed in section V. of this proposed rule.
- Describe the calculation of the IRF Standard Payment Conversion Factor for FY 2014, as discussed in section V. of this proposed rule.
- Update the outlier threshold amount for FY 2014, as discussed in section VI. of this proposed rule.
- Update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2014, as discussed in section VI. of this proposed rule.
- Describe proposed revisions to the list of eligible ICD–9–CM diagnosis codes that meet the presumptive compliance criteria in section VII. of this proposed rule.
- Describe proposed non-quality-related revisions to IRF–PAI sections in section VIII. of this proposed rule.
- 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 XIII. of this proposed rule.

B. Proposed Revisions to Existing Regulation Text

In this proposed rule, we are also proposing the following revisions to the existing regulations:

- Revisions to § 412.25(a)(1)(iii) to specify a minimum required number of beds that are not excluded from the inpatient prospective payment system (IPPS) for a hospital that has an IRF unit, as described in section X. of this proposed rule.
- Technical corrections to § 412.130, to reflect prior changes to the regulations at § 412.29 and § 412.30 that we made in the FY 2012 IRF PPS final rule (76 FR 47836), as described in section IX. of this proposed rule.
- Clarifications to § 412.630, to reflect the scope of section 1886(j)(8) of the Act, as described in section XI. of this proposed rule.
- Revision to § 412.29(d), to clarify that Medicare requires the rehabilitation physician's review and concurrence on the preadmission screening for Medicare Part A fee-for-service patients only, as described in section XII. of this proposed rule.

III. Proposed Update to the Case-Mix Group (CMG) Relative Weights and Average Length of Stay Values for FY 2014

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 this proposed rule, we propose to update the CMG relative weights and average length of stay values for FY 2014. 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 2014, we are proposing to use the FY 2012 IRF claims and FY 2011 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 2012 IRF cost report data are available for analysis, but the majority of the FY 2012 IRF claims data are available for analysis.

In this proposed rule, we propose to apply these data using the same methodologies that we have used to update the CMG relative weights and average length of stay values in the FY 2011 notice (75 FR 42836), the FY 2012 final rule (76 FR 47836), and the FY 2013 notice (77 FR 44618). 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 2014 CMG relative weights to the same average CMG relative weight from the CMG relative weights implemented in the FY 2013 IRF PPS notice (77 FR 44618).

Consistent with the methodology that we have used to update the IRF classification system in each instance in the past, we are proposing to update the CMG relative weights for FY 2014 in such a way that total estimated aggregate payments to IRFs for FY 2014 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 proposed budget neutrality factor for use in updating the FY 2014 CMG relative weights, we propose to use the following steps:

Step 1. Calculate the estimated total amount of IRF PPS payments for FY 2014 (with no proposed changes to the CMG relative weights).

Step 2. Calculate the estimated total amount of IRF PPS payments for FY 2014 by applying the proposed 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 proposed budget neutrality factor (1.0000) that would maintain the same total estimated aggregate payments in FY 2014 with and without the proposed changes to the CMG relative weights.

Step 4. Apply the proposed budget neutrality factor (1.0000) to the FY 2013 IRF PPS standard payment amount after the application of the budget-neutral wage adjustment factor.

In section V.E. of this proposed rule, we discuss the proposed use of the existing methodology to calculate the standard payment conversion factor for FY 2014.

Table 1, ''Proposed Relative Weights and Average Length of Stay Values for Case-Mix Groups,'' presents the CMGs, the comorbidity tiers, the proposed corresponding relative weights, and the proposed average length of stay values for each CMG and tier for FY 2014. 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. The proposed relative weights and average length of stay values shown in Table 1 are subject to change for the final rule if more recent data become available for use in these analyses.

TABLE 1—PROPOSED 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			
		Tier1	Tier2	Tier3	None	Tier1	Tier2	Tier3	None
0101	Stroke M>51.05	0.8001	0.7122	0.6556	0.6248	9	9	9	8
0102	Stroke M>44.45 and M<51.05 and C>18.5.	0.9921	0.8831	0.8129	0.7748	11	12	10	10
0103	Stroke M>44.45 and M<51.05 and C<18.5.	1.1613	1.0337	0.9516	0.9069	13	13	12	11
0104	Stroke M>38.85 and M<44.45	1.2210	1.0869	1.0006	0.9536	14	12	12	12
0105	Stroke M>34.25 and M<38.85	1.4283	1.2715	1.1704	1.1154	15	14	14	14
0106	Stroke M>30.05 and M<34.25	1.6327	1.4534	1.3379	1.2751	16	17	16	15
0107	Stroke M>26.15 and M<30.05	1.8413	1.6391	1.5088	1.4380	19	20	17	17
0108	Stroke M<26.15 and A>84.5	2.3160	2.0616	1.8978	1.8087	23	24	22	21
0109	Stroke M>22.35 and M<26.15 and A<84.5.	2.1034	1.8724	1.7236	1.6426	21	21	19	20
0110	Stroke M<22.35 and A<84.5	2.7387	2.4380	2.2443	2.1388	28	28	25	25
0201	Traumatic brain injury M>53.35 and C>23.5.	0.8068	0.6835	0.6059	0.5641	10	10	8	8
0202	Traumatic brain injury M>44.25 and M<53.35 and C>23.5.	1.0536	0.8926	0.7912	0.7366	12	10	10	10
0203	Traumatic brain injury M>44.25 and C<23.5.	1.2422	1.0524	0.9329	0.8685	14	13	12	11
0204	Traumatic brain injury M>40.65 and M<44.25.	1.3000	1.1013	0.9762	0.9089	12	13	12	12
0205	Traumatic brain injury M>28.75 and M<40.65.	1.5755	1.3347	1.1831	1.1015	17	16	14	14
0206	Traumatic brain injury M>22.05 and M<28.75.	1.9459	1.6485	1.4613	1.3605	18	19	17	16
0207	Traumatic brain injury M<22.05	2.5684	2.1759	1.9287	1.7957	33	26	21	20
0301	Non-traumatic brain injury M>41.05.	1.0992	0.9462	0.8502	0.7859	10	11	11	10
0302	Non-traumatic brain injury M>35.05 and M<41.05.	1.3735	1.1824	1.0625	0.9820	13	14	12	12
0303	Non-traumatic brain injury M>26.15 and M<35.05.	1.6221	1.3964	1.2548	1.1597	16	16	14	14
0304	Non-traumatic brain injury M<26.15.	2.1731	1.8708	1.6810	1.5537	24	21	19	18
0401	Traumatic spinal cord injury M>48.45.	1.1451	0.9494	0.8847	0.7923	13	13	11	10
0402	Traumatic spinal cord injury M>30.35 and M<48.45.	1.4139	1.1724	1.0924	0.9784	17	14	14	12
0403	Traumatic spinal cord injury M>16.05 and M<30.35.	2.3069	1.9128	1.7823	1.5963	26	23	20	20
0404	Traumatic spinal cord injury M<16.05 and A>63.5.	4.2117	3.4921	3.2539	2.9142	46	41	35	34
0405	Traumatic spinal cord injury M<16.05 and A<63.5.	3.4483	2.8592	2.6642	2.3861	37	32	31	27
0501	Non-traumatic spinal cord injury M>51.35.	0.8500	0.6729	0.6328	0.5761	9	9	8	8
0502	Non-traumatic spinal cord injury M>40.15 and M<51.35.	1.1064	0.8759	0.8237	0.7500	12	11	10	10
0503	Non-traumatic spinal cord injury M>31.25 and M<40.15.	1.4276	1.1302	1.0628	0.9677	15	13	13	12
0504	Non-traumatic spinal cord injury M>29.25 and M<31.25.	1.6534	1.3089	1.2309	1.1207	14	16	14	14
0505	Non-traumatic spinal cord injury M>23.75 and M<29.25.	1.9495	1.5433	1.4514	1.3214	21	18	17	16
0506	Non-traumatic spinal cord injury M<23.75.	2.7308	2.1619	2.0330	1.8510	30	25	23	21
0601	Neurological M>47.75	0.9661	0.7875	0.7272	0.6589	10	10	9	9
0602	Neurological M>37.35 and M<47.75.	1.2904	1.0518	0.9713	0.8801	12	12	11	11
0603	Neurological M>25.85 and M<37.35.	1.6184	1.3191	1.2182	1.1038	15	15	14	13
0604	Neurological M<25.85	2.1563	1.7575	1.6231	1.4706	22	19	18	17
0701	Fracture of lower extremity M>42.15.	0.9445	0.8052	0.7712	0.6996	10	10	10	9
0702	Fracture of lower extremity M>34.15 and M<42.15.	1.2149	1.0357	0.9920	0.8999	12	12	12	11
0703	Fracture of lower extremity M>28.15 and M<34.15.	1.4770	1.2591	1.2060	1.0940	15	15	14	13
0704	Fracture of lower extremity M<28.15.	1.8753	1.5987	1.5312	1.3891	18	18	18	17

TABLE 1—PROPOSED 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			
		Tier1	Tier2	Tier3	None	Tier1	Tier2	Tier3	None
0801	Replacement of lower extremity joint M>49.55.	0.7009	0.6238	0.5675	0.5200	7	8	7	7
0802	Replacement of lower extremity joint M>37.05 and M<49.55.	0.9206	0.8193	0.7453	0.6830	10	10	9	9
0803	Replacement of lower extremity joint M>28.65 and M<37.05 and A>83.5.	1.2478	1.1105	1.0103	0.9257	12	13	13	12
0804	Replacement of lower extremity joint M>28.65 and M<37.05 and A<83.5.	1.1083	0.9863	0.8973	0.8222	11	12	11	10
0805	Replacement of lower extremity joint M>22.05 and M<28.65.	1.3678	1.2173	1.1075	1.0148	15	15	13	12
0806	Replacement of lower extremity joint M<22.05.	1.6590	1.4765	1.3433	1.2308	17	17	15	15
0901	Other orthopedic M>44.75	0.9026	0.7480	0.6895	0.6254	11	9	9	8
0902	Other orthopedic M>34.35 and M<44.75.	1.2051	0.9987	0.9206	0.8350	12	12	11	11
0903	Other orthopedic M>24.15 and M<34.35.	1.5094	1.2509	1.1530	1.0459	15	15	14	13
0904	Other orthopedic M<24.15	1.9660	1.6293	1.5019	1.3623	19	18	17	16
1001	Amputation, lower extremity M>47.65.	1.0372	0.9443	0.8131	0.7478	12	11	10	10
1002	Amputation, lower extremity M>36.25 and M<47.65.	1.3081	1.1909	1.0255	0.9431	13	13	12	12
1003	Amputation, lower extremity M<36.25.	1.9330	1.7599	1.5154	1.3936	19	20	17	16
1101	Amputation, non-lower extremity M>36.35.	1.2388	1.1334	1.0487	1.0147	13	13	12	12
1102	Amputation, non-lower extremity M<36.35.	1.7069	1.5618	1.4450	1.3981	16	17	16	16
1201	Osteoarthritis M>37.65	0.9482	0.9350	0.8467	0.7752	9	11	10	10
1202	Osteoarthritis M>30.75 and M<37.65.	1.1813	1.1649	1.0549	0.9659	14	14	13	12
1203	Osteoarthritis M<30.75	1.4671	1.4468	1.3101	1.1995	13	17	15	14
1301	Rheumatoid, other arthritis M>36.35.	1.1815	0.9991	0.9005	0.8171	12	10	11	10
1302	Rheumatoid, other arthritis M>26.15 and M<36.35.	1.5305	1.2942	1.1666	1.0585	16	15	14	13
1303	Rheumatoid, other arthritis M<26.15.	1.9677	1.6639	1.4998	1.3608	18	19	17	16
1401	Cardiac M>48.85	0.8864	0.7216	0.6539	0.5919	9	9	9	8
1402	Cardiac M>38.55 and M<48.85	1.1973	0.9747	0.8832	0.7995	12	11	11	10
1403	Cardiac M>31.15 and M<38.55	1.4604	1.1889	1.0773	0.9752	14	14	12	12
1404	Cardiac M<31.15	1.8618	1.5157	1.3734	1.2433	19	17	15	14
1501	Pulmonary M>49.25	1.0003	0.8590	0.7747	0.7436	10	9	9	9
1502	Pulmonary M>39.05 and M<49.25.	1.2590	1.0812	0.9751	0.9359	12	12	11	11
1503	Pulmonary M>29.15 and M<39.05.	1.5224	1.3074	1.1791	1.1318	15	14	13	13
1504	Pulmonary M<29.15	1.8896	1.6227	1.4634	1.4047	21	17	16	15
1601	Pain syndrome M>37.15	1.0309	0.8817	0.8282	0.7568	9	10	10	9
1602	Pain syndrome M>26.75 and M<37.15.	1.3536	1.1577	1.0874	0.9937	12	14	13	12
1603	Pain syndrome M<26.75	1.7052	1.4584	1.3699	1.2518	18	17	15	15
1701	Major multiple trauma without brain or spinal cord injury M>39.25.	1.0875	0.9493	0.8541	0.7718	11	12	11	10
1702	Major multiple trauma without brain or spinal cord injury M>31.05 and M<39.25.	1.3611	1.1881	1.0689	0.9659	13	14	13	12
1703	Major multiple trauma without brain or spinal cord injury M>25.55 and M<31.05.	1.6427	1.4339	1.2901	1.1658	17	16	14	14
1704	Major multiple trauma without brain or spinal cord injury M<25.55.	2.0841	1.8193	1.6368	1.4790	24	20	18	18
1801	Major multiple trauma with brain or spinal cord injury M>40.85.	1.1476	1.0623	0.9340	0.7874	14	13	12	10

TABLE 1—PROPOSED 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			
		Tier1	Tier2	Tier3	None	Tier1	Tier2	Tier3	None
1802	Major multiple trauma with brain or spinal cord injury M>23.05 and M<40.85.	1.7108	1.5837	1.3924	1.1739	18	19	17	14
1803	Major multiple trauma with brain or spinal cord injury M<23.05.	2.7350	2.5317	2.2259	1.8766	32	28	23	22
1901	Guillain Barre M>35.95	1.0958	0.9305	0.9064	0.8886	13	10	11	11
1902	Guillain Barre M>18.05 and M<35.95.	2.1340	1.8120	1.7652	1.7305	23	21	18	20
1903	Guillain Barre M<18.05	3.5000	2.9719	2.8951	2.8382	41	32	31	30
2001	Miscellaneous M>49.15	0.8897	0.7304	0.6716	0.6138	9	9	8	8
2002	Miscellaneous M>38.75 and M<49.15.	1.1865	0.9741	0.8956	0.8186	12	11	11	10
2003	Miscellaneous M>27.85 and M<38.75.	1.4910	1.2241	1.1254	1.0286	14	14	13	12
2004	Miscellaneous M<27.85	1.9537	1.6039	1.4746	1.3478	20	18	17	15
2101	Burns M>0	2.1782	1.5737	1.4885	1.4056	24	21	17	16
5001	Short-stay cases, length of stay is 3 days or fewer.				0.1541				3
5101	Expired, orthopedic, length of stay is 13 days or fewer.				0.6604				8
5102	Expired, orthopedic, length of stay is 14 days or more.				1.4552				17
5103	Expired, not orthopedic, length of stay is 15 days or fewer.				0.7653				9
5104	Expired, not orthopedic, length of stay is 16 days or more.				1.9930				22

Generally, updates to the CMG relative weights result in some increases and some decreases to the CMG relative weight values. Table 2 shows how the application of the proposed revisions for FY 2014 would affect particular CMG relative weight values, which 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 2014 would not be affected as a result of the CMG relative weight revisions. However, the proposed revisions would affect the distribution of payments within CMGs and tiers.

TABLE 2—DISTRIBUTIONAL EFFECTS OF THE PROPOSED CHANGES TO THE CMG RELATIVE WEIGHTS

[FY 2013 Values Compared With FY 2014 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%	2,325	0.7
Changed by less than 5%	340,496	98.7
Decreased by between 5% and 15%	1,939	0.6
Decreased by 15% or more	92	0.0

As Table 2 shows, almost 99 percent of all IRF cases are in CMGs and tiers that would experience less than a 5 percent change (either increase or decrease) in the CMG relative weight value as a result of the proposed revisions for FY 2014. The largest increase in the proposed CMG relative weight values that affects a particularly large number of IRF discharges is a 0.9 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 2012 data, 18,770 IRF discharges (5.4 percent of all IRF discharges) were classified into this CMG and tier.

The largest decrease in a CMG relative weight value affecting the most cases is a 2.0 percent decrease in the CMG relative weight for CMG 0903—Other Orthopedic with a motor score between 24.15 and 34.35—in the no comorbidity tier. In the FY 2012 IRF claims data, this change affects 6,605 cases (1.9 percent of all IRF cases).

The changes in the average length of stay values for FY 2014, compared with the FY 2013 average length of stay values, are small and do not show any particular trends in IRF length of stay patterns.

IV. Proposed Updates to the Facility-Level Adjustment Factors for FY 2014

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 at 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 un-weighted 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. Proposed Updates to the IRF Facility-Level Adjustment Factors

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 have shown that significant differences 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, we propose 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 and 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 41 percent). In this way, it enhances the precision with which we can estimate the IRF facility-level adjustments.

Therefore, in this proposed rule, we propose to use the same methodology used in the FY 2010 IRF PPS final rule (74 FR 39762), including the 3-year moving average approach, with the addition of this new control variable, which equals ''1'' if the facility is a freestanding IRF hospital and ''0'' if it is an IRF unit of an acute care hospital (or a CAH). We propose to update the adjustment factors using the most recent three years' worth of IRF claims data (FY 2010, FY 2011, and FY 2012) and the most recent available corresponding IRF cost report data. As we did in the FY 2010 IRF PPS final rule (74 FR 39762), we propose to use the cost report data that corresponds with each IRF claim, when available. In the rare instances in which the corresponding year's cost report data are not available, we propose to use the most recent available cost report data, as we also did in the FY 2010 IRF PPS final rule (74 FR 39762).

To calculate the proposed updates to the rural, LIP, and teaching status adjustment factors for FY 2014, we propose to use the following steps:

[Steps 1 and 2 are performed independently for each of three years of IRF claims data: FY 2010, FY 2011, and FY 2012.]

Step 1. Calculate the average cost per case for each IRF in the IRF claims data.

Step 2. Use logarithmic regression analysis on average cost per case to compute the coefficients for the rural, LIP, and teaching status adjustments. We are also proposing to incorporate an additional indicator variable to account for whether a facility is a freestanding IRF hospital or a unit of an acute care hospital (or a CAH).

Step 3. Calculate a simple mean for each of the coefficients across the three years of data (using logarithms for the LIP and teaching status adjustment coefficients (because they are continuous variables), but not for the rural adjustment coefficient (because the rural variable is either zero (if not rural) or 1 (if rural)). To compute the LIP and teaching status adjustment factors, we convert these factors back out of the logarithmic form.

Based on this methodology, we propose to update the rural adjustment factor for FY 2014 from 18.4 percent to 14.28 percent. We propose to update the LIP adjustment factor for FY 2014 from 0.4613 to 0.3158 and the teaching status adjustment factor for FY 2014 from 0.6876 to 0.9859. The proposed adjustment factors are subject to change

for the final rule if more data become available for use in these analyses.

Further, although we believe that updating the facility-level adjustment factors with the proposed methodology will enhance the accuracy and fairness of the IRF PPS payment rates, we recognize that this would result in significant financial impacts for IRF providers. Thus, we welcome comments from the industry on whether updating the adjustment factors at this time or freezing them at the current levels for an additional year would be a better approach.

C. Budget Neutrality Methodology for the Updates to the IRF Facility-Level Adjustment Factors

Consistent with the way that we implemented changes to the IRF facility-level adjustment factors (the rural, LIP, and teaching status adjustments factors) in the FY 2006 IRF PPS final rule (70 FR 47880 and 70 FR 57166), which was the only year in which we updated these adjustment factors, we propose to make changes to the rural, LIP, and teaching status adjustment factors for FY 2014 in such a way that total estimated aggregate payments to IRFs for FY 2014 would be the same with or without the proposed changes (that is, in a budget neutral manner) by applying budget neutrality factors for each of these three changes to the standard payment amount. To calculate the proposed budget neutrality factors used to update the rural, LIP, and teaching status adjustment factors, we propose to use the following steps:

Step 1. Using the most recent available data (currently FY 2011), calculate the estimated total amount of IRF PPS payments that would be made in FY 2014 (without applying the proposed changes to the rural, LIP, or teaching status adjustment factors).

Step 2. Calculate the estimated total amount of IRF PPS payments that would be made in FY 2014 if the proposed update to the rural adjustment factor were applied.

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2 to determine the proposed budget neutrality factor (1.0030) that would maintain the same total estimated aggregate payments in FY 2014 with and without the proposed change to the rural adjustment factor.

Step 4. Calculate the estimated total amount of IRF PPS payments that would be made in FY 2014 if the proposed update to the LIP adjustment factor were applied.

Step 5. Divide the amount calculated in step 1 by the amount calculated in step 4 to determine the proposed budget neutrality factor (1.0174) that would maintain the same total estimated aggregate payments in FY 2014 with and without the proposed change to the LIP adjustment factor.

Step 6. Calculate the estimated total amount of IRF PPS payments that would be made in FY 2014 if the proposed update to the teaching status adjustment factor were applied.

Step 7. Divide the amount calculated in step 1 by the amount calculated in step 6 to determine the proposed budget neutrality factor (0.9966) that would maintain the same total estimated aggregate payments in FY 2014 with and without the proposed change to the teaching status adjustment factor.

Step 8. Apply the proposed budget neutrality factors for the updates to the rural, LIP, and teaching status adjustment factors to the FY 2013 IRF PPS standard payment amount after the application of the proposed budget neutrality factors for the wage adjustment and the CMG relative weights.

The proposed budget neutrality factors for the proposed changes to the rural, LIP, and teaching status adjustment factors are subject to change in the final rule if more recent data become available for use in these analyses or if the proposed payment policies associated with the proposed budget neutrality factors change. In section V.E of this proposed rule, we discuss the proposed methodology for calculating the standard payment conversion factor for FY 2014.

V. Proposed FY 2014 IRF PPS Federal Prospective Payment Rates

A. Proposed Market Basket Increase Factor, Productivity Adjustment, Other Adjustment, and Secretary's Recommendation for FY 2014

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)(iii) of the Act required the application of a 0.3 percentage point reduction to the market basket increase factor for FY 2014. In addition, section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment, as described below. Thus, in this proposed rule, we are proposing to update the IRF PPS payments for FY 2014 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 0.3 percentage point reduction as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iii) of the Act.

For this proposed rule, we propose to use the same methodology described in the FY 2012 IRF PPS final rule (76 FR 47836 at 47848 through 47863) to compute the FY 2014 market basket increase factor and labor-related share. In that final rule, we rebased the RPL market basket from a 2002 base year to a 2008 base year. Based on IHS Global Insight's first quarter 2013 forecast, the most recent estimate of the 2008-based RPL market basket increase factor for FY 2014 is 2.5 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 propose to apply a productivity adjustment to the FY 2014 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 2014 (the 10-year moving average of MFP for the period ending FY 2014) is 0.4 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 first quarter 2013 forecast.

Thus, in accordance with section 1886(j)(3)(C) of the Act, we propose to base the FY 2014 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

2.5 percent based on IGI's first quarter 2013 forecast). We propose to then reduce this percentage increase by the current estimate of the MFP adjustment for FY 2014 of 0.4 percentage point (the 10-year moving average of MFP for the period ending FY 2014 based on IGI's first quarter 2013 forecast), which was calculated as described in the FY 2012 IRF PPS final rule (76 FR 47836, 47859). Following application of the productivity adjustment, we propose to further reduce the applicable percentage increase by 0.3 percentage point, as required by sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(iii) of the Act. Therefore, the current estimate of the proposed FY 2014 IRF update is 1.8 percent (2.5 percent market basket update less 0.4 percentage point MFP adjustment less 0.3 percentage point legislative adjustment). Furthermore, we also are proposing 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 2014 market basket update and MFP adjustment in the final rule.

B. Secretary's Proposed Recommendation

For FY 2014, the Medicare Payment Advisory Commission (MedPAC) recommends that a 0 percent update be applied to IRF PPS payment rates for FY 2013. As discussed above, and in accordance with sections 1886(j)(3)(C) and 1886(j)(3)(D) of the Act, the Secretary is proposing to update IRF PPS payment rates for FY 2014 by an adjusted market basket increase factor of 1.8 percent because 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 2014.

C. Proposed Labor-Related Share for FY 2014

The proposed labor-related share for FY 2014 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 first quarter 2013 forecast of the 2008-based RPL market basket, the proposed IRF labor-related share for FY 2014 is the sum of the FY 2014 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 2014. As shown in Table 3, the proposed FY 2014 labor-related share is 69.658 percent. We propose that if a more recent estimate of the FY 2014 labor-related share is subsequently available, we would use such data, if appropriate, to determine the FY 2014 labor-related share in the final rule.

TABLE 3—PROPOSED FY 2014 IRF RPL LABOR-RELATED SHARE RELATIVE IMPORTANCE

	Proposed FY 2014 Relative Importance Labor-Related Share
Wages and Salaries	48.491
Employee Benefits	13.019
Professional Fees: Labor-Related	2.069
Administrative and Business Support Services	0.417
All Other: Labor-Related Services	2.086
Subtotal	66.082
Labor-Related Portion of Capital Costs (.46)	3.576
Total Labor-Related Share	69.658

Source: IHS Global Insight, Inc. 1st quarter 2013 forecast; Historical Data through 4th quarter, 2012.

D. Proposed Area 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.

In the FY 2009 IRF PPS final rule (73 FR 46378), we maintained the methodology described in the FY 2006 IRF PPS final rule to determine the wage index, labor market area definitions and hold harmless policy consistent with the rationale outlined in the FY 2006 IRF PPS final rule (70 FR 47880, 47917 through 47926).

For FY 2014, we are maintaining the policies and methodologies described in the FY 2012 IRF PPS final rule (76 FR 47836, at 47863 through 47865) relating 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 2013 pre-reclassification and pre-floor hospital wage index data. In accordance with section 1886(d)(3)(E) of the Act, the FY 2013 pre-reclassification and pre-floor hospital wage index is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2008, and before October 1, 2009 (that is, FY 2009 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 propose to 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 in which to base the calculation for the FY 2014 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 propose to use the prior year's (FY 2013) pre-floor, pre-reclassified hospital wage index data to derive the FY 2014 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 proposed 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. This bulletin contains a number of significant changes. For example, there are new CBSAs, counties that change from urban to rural, counties that change from rural to urban, and existing CBSAs that are being split apart. The OMB Bulletin with these changes was not published in time for us to incorporate these changes into the FY 2014 pre-floor, pre-reclassified hospital wage index, since the proposed rule was already in the advanced stages of development at that time and the changes and their ramifications would need to be extensively reviewed and verified prior to their inclusion in the rule. We therefore intend to propose the incorporation of these CBSA changes in our 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 reflected in the IRF PPS wage index until FY 2016.

To calculate the wage-adjusted facility payment for the payment rates set forth in this proposed rule, we multiply the unadjusted Federal payment rate for IRFs by the proposed FY 2014 labor-related share based on the FY 2008-based RPL market basket (69.658 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 proposed 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 proposed 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 proposed FY 2014 IRF standard payment conversion factor reflects the update to the wage indexes (based on the FY 2009 hospital cost report data) and the proposed labor-related share in a budget neutral manner:

Step 1. Determine the total amount of the estimated FY 2013 IRF PPS rates, using the FY 2013 standard payment conversion factor and the labor-related share and the wage indexes from FY 2013 (as published in the FY 2013 IRF PPS notice (77 FR 44618)).

Step 2. Calculate the total amount of estimated IRF PPS payments using the FY 2013 standard payment conversion factor and the proposed FY 2014 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 proposed FY 2014 budget neutral wage adjustment factor of 1.0011.

Step 4. Apply the proposed FY 2014 budget neutral wage adjustment factor from step 3 to the FY 2013 IRF PPS standard payment conversion factor after the application of the adjusted market basket update to determine the proposed FY 2014 standard payment conversion factor.

We discuss the calculation of the proposed standard payment conversion factor for FY 2014 in section V.E. of this proposed rule.

E. Description of the Proposed IRF Standard Conversion Factor and Payment Rates for FY 2014

To calculate the proposed standard payment conversion factor for FY 2014, as illustrated in Table 4, we begin by applying the proposed adjusted market basket increase factor for FY 2014 that was adjusted in accordance with sections 1886(j)(3)(C) and (D) of the Act, to the standard payment conversion factor for FY 2013 ($14,343). Applying the proposed 1.8 percent adjusted market basket increase factor for FY 2014 to the revised standard payment conversion factor for FY 2013 of $14,343 yields a standard payment amount of $14,601. Then, we apply the proposed budget neutrality factor for the FY 2014 wage index and labor-related share of 1.0011, which results in a standard payment amount of $14,617. We next apply the proposed budget neutrality factors for the revised CMG relative weights of 1.0000, which results in a standard payment conversion factor of $14,617 for FY 2014.

We then apply the proposed budget neutrality factors for the facility adjustments. Applying the budget neutrality factor for the revised rural adjustment of 1.0030 results in a standard payment conversion factor of $14,661. We then apply the budget neutrality factor for the revised LIP adjustment of 1.0174 resulting in a standard payment conversion factor of $14,916. Lastly, we apply the budget neutrality factor for the revised teaching adjustment of 0.9966 which results in a final standard payment conversion factor of $14,865.

TABLE 4—CALCULATIONS TO DETERMINE THE PROPOSED FY 2014 STANDARD PAYMENT CONVERSION FACTOR

Explanation for adjustment	Calculations
Standard Payment Conversion Factor for FY 2013	$14,343
Market Basket Increase Factor for FY 2014 (2.5 percent), reduced by 0.3 percentage point in accordance with sections 1886(j)(3)(C) and (D) of the Act and a 0.4 percentage point reduction for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act	× 1.018
Budget Neutrality Factor for the Wage Index and Labor-Related Share	× 1.0011
Budget Neutrality Factor for the Revisions to the CMG Relative Weights	× 1.0000
Budget Neutrality Factor for the Update to the Rural Adjustment Factor	× 1.0030
Budget Neutrality Factor for the Update to the LIP Adjustment Factor	× 1.0174
Budget Neutrality Factor for the Update to the Teaching Status Adjustment Factor	× 0.9966
Proposed FY 2014 Standard Payment Conversion Factor	= 14,865

After the application of the CMG relative weights described in Section III of this proposed rule, to the proposed FY 2014 standard payment conversion factor ($14,865), the resulting proposed unadjusted IRF prospective payment rates for FY 2014 are shown in Table 5.

TABLE 5—PROPOSED FY 2014 PAYMENT RATES

CMG	Payment rate tier 1	Payment rate tier 2	Payment rate tier 3	Payment rate no comorbidity
0101	$ 11,893.49	$ 10,586.85	$ 9,745.49	$ 9,287.65
0102	14,747.57	13,127.28	12,083.76	11,517.40
0103	17,262.72	15,365.95	14,145.53	13,481.07
0104	18,150.17	16,156.77	14,873.92	14,175.26
0105	21,231.68	18,900.85	17,398.00	16,580.42
0106	24,270.09	21,604.79	19,887.88	18,954.36
0107	27,370.92	24,365.22	22,428.31	21,375.87
0108	34,427.34	30,645.68	28,210.80	26,886.33
0109	31,267.04	27,833.23	25,621.31	24,417.25
0110	40,710.78	36,240.87	33,361.52	31,793.26
0201	11,993.08	10,160.23	9,006.70	8,385.35
0202	15,661.76	13,268.50	11,761.19	10,949.56
0203	18,465.30	15,643.93	13,867.56	12,910.25
0204	19,324.50	16,370.82	14,511.21	13,510.80
0205	23,419.81	19,840.32	17,586.78	16,373.80
0206	28,925.80	24,504.95	21,722.22	20,223.83
0207	38,179.27	32,344.75	28,670.13	26,693.08
0301	16,339.61	14,065.26	12,638.22	11,682.40
0302	20,417.08	17,576.38	15,794.06	14,597.43
0303	24,112.52	20,757.49	18,652.60	17,238.94
0304	32,303.13	27,809.44	24,988.07	23,095.75
0401	17,021.91	14,112.83	13,151.07	11,777.54
0402	21,017.62	17,427.73	16,238.53	14,543.92
0403	34,292.07	28,433.77	26,493.89	23,729.00
0404	62,606.92	51,910.07	48,369.22	43,319.58
0405	51,258.98	42,502.01	39,603.33	35,469.38
0501	12,635.25	10,002.66	9,406.57	8,563.73
0502	16,446.64	13,020.25	12,244.30	11,148.75
0503	21,221.27	16,800.42	15,798.52	14,384.86
0504	24,577.79	19,456.80	18,297.33	16,659.21
0505	28,979.32	22,941.15	21,575.06	19,642.61
0506	40,593.34	32,136.64	30,220.55	27,515.12
0601	14,361.08	11,706.19	10,809.83	9,794.55
0602	19,181.80	15,635.01	14,438.37	13,082.69
0603	24,057.52	19,608.42	18,108.54	16,407.99
0604	32,053.40	26,125.24	24,127.38	21,860.47
0701	14,039.99	11,969.30	11,463.89	10,399.55
0702	18,059.49	15,395.68	14,746.08	13,377.01
0703	21,955.61	18,716.52	17,927.19	16,262.31
0704	27,876.33	23,764.68	22,761.29	20,648.97
0801	10,418.88	9,272.79	8,435.89	7,729.80
0802	13,684.72	12,178.89	11,078.88	10,152.80
0803	18,548.55	16,507.58	15,018.11	13,760.53
0804	16,474.88	14,661.35	13,338.36	12,222.00
0805	20,332.35	18,095.16	16,462.99	15,085.00
0806	24,661.04	21,948.17	19,968.15	18,295.84
0901	13,417.15	11,119.02	10,249.42	9,296.57
0902	17,913.81	14,845.68	13,684.72	12,412.28
0903	22,437.23	18,594.63	17,139.35	15,547.30
0904	29,224.59	24,219.54	22,325.74	20,250.59
1001	15,417.98	14,037.02	12,086.73	11,116.05
1002	19,444.91	17,702.73	15,244.06	14,019.18
1003	28,734.05	26,160.91	22,526.42	20,715.86
1101	18,414.76	16,847.99	15,588.93	15,083.52
1102	25,373.07	23,216.16	21,479.93	20,782.76
1201	14,094.99	13,898.78	12,586.20	11,523.35
1202	17,560.02	17,316.24	15,681.09	14,358.10
1203	21,808.44	21,506.68	19,474.64	17,830.57
1301	17,563.00	14,851.62	13,385.93	12,146.19
1302	22,750.88	19,238.28	17,341.51	15,734.60
1303	29,249.86	24,733.87	22,294.53	20,228.29
1401	13,176.34	10,726.58	9,720.22	8,798.59
1402	17,797.86	14,488.92	13,128.77	11,884.57
1403	21,708.85	17,673.00	16,014.06	14,496.35
1404	27,675.66	22,530.88	20,415.59	18,481.65
1501	14,869.46	12,769.04	11,515.92	11,053.61
1502	18,715.04	16,072.04	14,494.86	13,912.15
1503	22,630.48	19,434.50	17,527.32	16,824.21
1504	28,088.90	24,121.44	21,753.44	20,880.87
1601	15,324.33	13,106.47	12,311.19	11,249.83
1602	20,121.26	17,209.21	16,164.20	14,771.35

TABLE 5—PROPOSED FY 2014 PAYMENT RATES—Continued

CMG	Payment rate tier 1	Payment rate tier 2	Payment rate tier 3	Payment rate no comorbidity
1603	25,347.80	21,679.12	20,363.56	18,608.01
1701	16,165.69	14,111.34	12,696.20	11,472.81
1702	20,232.75	17,661.11	15,889.20	14,358.10
1703	24,418.74	21,314.92	19,177.34	17,329.62
1704	30,980.15	27,043.89	24,331.03	21,985.34
1801	17,059.07	15,791.09	13,883.91	11,704.70
1802	25,431.04	23,541.70	20,698.03	17,450.02
1803	40,655.78	37,633.72	33,088.00	27,895.66
1901	16,289.07	13,831.88	13,473.64	13,209.04
1902	31,721.91	26,935.38	26,239.70	25,723.88
1903	52,027.50	44,177.29	43,035.66	42,189.84
2001	13,225.39	10,857.40	9,983.33	9,124.14
2002	17,637.32	14,480.00	13,313.09	12,168.49
2003	22,163.72	18,196.25	16,729.07	15,290.14
2004	29,041.75	23,841.97	21,919.93	20,035.05
2101	32,378.94	23,393.05	22,126.55	20,894.24
5001				2,290.70
5101				9,816.85
5102				21,631.55
5103				11,376.18
5104				29,625.95

F. Example of the Methodology for Adjusting the Proposed Federal Prospective Payment Rates

Table 6 illustrates the methodology for adjusting the proposed federal prospective payments (as described in sections V.A. through V.C. of this proposed rule). The following examples are based on two hypothetical Medicare beneficiaries, both classified into CMG 0110 (without comorbidities). The proposed unadjusted federal prospective payment rate for CMG 0110 (without comorbidities) appears in Table 5.

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 1.0155), a wage index of 0.8472, and a rural adjustment of 14.28 percent. Facility B, an urban teaching hospital, has a DSH percentage of 15 percent (which would result in a LIP adjustment of 1.0451 percent), a wage index of 0.8862, and a teaching status adjustment of 0.0610.

To calculate each IRF's labor and non-labor portion of the proposed Federal prospective payment, we begin by taking the proposed unadjusted Federal prospective payment rate for CMG 0110 (without comorbidities) from Table 5. Then, we multiply the proposed labor-related share for FY 2014 (69.658 percent) described in section V.C. of this proposed rule by the proposed unadjusted federal prospective payment rate. To determine the non-labor portion of the proposed federal prospective payment rate, we subtract the labor portion of the proposed federal payment from the proposed unadjusted Federal prospective payment.

To compute the proposed wage-adjusted federal prospective payment, we multiply the labor portion of the proposed 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://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/*. The resulting figure is the wage-adjusted labor amount. Next, we compute the proposed wage-adjusted federal payment by adding the wage-adjusted labor amount to the non-labor portion.

Adjusting the proposed 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 (0.0610, 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 2014 FEDERAL PROSPECTIVE PAYMENT

Steps		Rural facility A (Spencer Co., IN)		Urban facility B (Harrison Co., IN)	
1	Unadjusted Federal Prospective Payment		$ 31,793.26		$ 31,793.26
2	Labor Share	×	0.69658	×	0.69658
3	Labor Portion of Federal Payment	=	22,146.55	=	22,146.55
4	CBSA Based Wage Index (shown in the Addendum , Tables 1 and 2)	×	0.8472	×	0.8862
5	Wage-Adjusted Amount	=	18,762.56	=	19,626.27
6	Nonlabor Amount	+	9,646.71	+	9,646.71
7	Wage-Adjusted Federal Payment	=	28,409.27	=	29,272.98
8	Rural Adjustment	×	1.1428	×	1.000
9	Wage- and Rural- Adjusted Federal Payment	=	32,466.11	=	29,272.98
10	LIP Adjustment	×	1.0155	×	1.0451
11	FY 2014 Wage-, Rural- and LIP- Adjusted Federal Prospective Payment Rate	=	32,969.33	=	30,593.19
12	FY 2014 Wage- and Rural-Adjusted Federal Prospective Payment		32,466.11		29,272.98
13	Teaching Status Adjustment	×	0	×	0.0610
14	Teaching Status Adjustment Amount	=	0.00	=	1,785.65
15	FY 2014 Wage-, Rural-, and LIP-Adjusted Federal Prospective Payment Rate	+	32,969.33	+	30,593.19

TABLE 6—EXAMPLE OF COMPUTING THE IRF FY 2014 FEDERAL PROSPECTIVE PAYMENT—Continued

16	Total FY 2014 Adjusted Federal Prospective Payment	=	32,969.33	=	32,378.84

Thus, the proposed adjusted payment for Facility A would be $32,969.33 and the proposed adjusted payment for Facility B would be $32,378.84.

VI. Proposed Update to Payments for High-Cost Outliers Under the IRF PPS

A. Proposed Update to the Outlier Threshold Amount for FY 2014

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 2012 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, 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 2014, we propose to use FY 2012 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 2013. 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 propose to update the outlier threshold amount to $10,111 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2014.

B. Proposed Update to the IRF Cost-to-Charge Ratio Urban and Rural Ceilings

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 propose to update the national urban and rural CCRs for IRFs, as well as the national CCR ceiling for FY 2014, 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 2014, as discussed below.
- Other IRFs for which accurate data to calculate an overall CCR are not available.

Specifically, for FY 2014, we estimate a proposed national average CCR of 0.638 for rural IRFs, which we calculate 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 0.511 for urban IRFs, which we calculate 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 proposed rule, we have used the most recent available cost report data (FY 2011). This includes all IRFs whose cost reporting periods begin on or after October 1, 2010, and before October 1, 2011. If, for any IRF, the FY 2011 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 2010) 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 propose to set the national CCR ceiling at 3 standard deviations above the mean CCR. Using this method, the national CCR ceiling is set at 1.43 for FY 2014. This means that, if an individual IRF's CCR exceeds this ceiling of 1.43 for FY 2014, 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 estimate 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 note that the proposed national average rural and urban CCRs and our estimate of the national CCR ceiling in this section are subject to change in the final rule if more recent data become available for use in these analyses.

VII. Proposed Refinements to the Presumptive Compliance Criteria Methodology

A. Background on the Compliance Percentage

The compliance percentage has been part of the criteria for defining IRFs

since implementation of the 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 vasculidities 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 was 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 a ''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 60 percent rule compliance criteria to ensure that the higher Medicare payments are appropriately allocated to those providers that are providing IRF-level services.

B. Proposed Changes to the ICD–9–CM Codes That Meet the Presumptive Compliance Criteria

The presumptive methodology is one of two ways that contractors may evaluate an IRF's compliance with the 60 percent rule compliance criteria (the other methodology is called the medical review methodology). IRFs may be evaluated using the presumptive methodology only if their Medicare fee-for-service and Medicare Advantage populations combined make-up over half of their total patient populations, so that the Medicare populations can be presumed to be representative of the IRF's total patient population. Thus, if an IRF is eligible to use the presumptive methodology to evaluate its compliance with the IRF 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 list. Under the rule, each IRF is given the option of whether the Medicare contractor reviews all IRF discharges from that period, or all admissions from that period. 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–9–CM 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 10 comorbidities on the assessment. An impairment group code is not an ICD–9–CM 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. The ICD–9–CM diagnosis codes that may be used to categorize a patient as meeting the 60 percent rule criteria if those codes appear on the patient's IRF–PAI assessment as either the etiologic diagnosis or as a comorbid condition are listed in ''Appendix C: ICD–9–CM Codes That Meet Presumptive Compliance Criteria.'' This list 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*.

The underlying premise of the presumptive methodology ICD–9–CM code list is that it represents those codes that would be expected to ''presumptively'' meet the 60 percent rule compliance criteria. That is, it reflects those particular diagnosis codes that, if a patient is coded using one of those codes, would more than likely be expected to meet the requirement either that the patient required intensive rehabilitation services for treatment of one or more of the conditions specified at § 412.29(b)(2) or 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 inpatient rehabilitation facilities and cannot be appropriately performed in another care setting.

Recently, we began a close examination of the list of ICD–9–CM codes that are currently deemed to meet the 60 percent rule under the presumptive method to begin the process of converting this code list to ICD–10–CM. Upon this examination, we found that changes over time (including changes in the use of the individual codes, changes in clinical practice, changes in the frequency of various types of illness and disability, and changes to the application of 60 percent rule itself) supported our updating the ICD–9–CM codes that are deemed to count toward a facility's 60 percent rule compliance. Such updates would ensure that the codes better reflect the regulations at § 412.29(b).

Our review included taking a fresh look at the regulations in § 412.29(b), which revealed that the following parts of the regulation were not being adequately addressed in the current application of the presumptive method of calculating compliance with the IRF 60 percent rule:

- The details of the requirements in paragraph § 412.29(b)(1), which specify that the IRF must serve ''an inpatient population of whom at least 60 percent required intensive rehabilitation services for treatment of one or more of the conditions specified . . .'', and
- The details of the requirements regarding the specific conditions under which a patient's comorbidity may be used to show that a patient meets the 60 percent rule criteria, specifically that, ''The comorbidity 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 inpatient rehabilitation facilities . . . and that cannot be appropriately performed in another care setting . . .''

These requirements must be met in conjunction with a patient having one of the 13 conditions listed in § 412.29(b)(2) for the case to meet the 60 percent rule compliance criteria. It is not enough for the patient to just have one of the 13 conditions. Mindful of these requirements, we took a fresh look at the ICD–9–CM codes on the presumptive methodology list.

Further, the regulations in § 412.29 also specify that the arthritis conditions only meet the 60 percent rule compliance criteria if certain severity and prior treatment criteria are met. It is impossible to discern from the ICD–9–CM codes themselves whether or not the required severity and prior treatment criteria are met for those patients being treated for arthritis conditions. This type of information can only be assessed on medical review. Thus, we found that the presence of the ICD–9–CM code, by itself, cannot allow us to presume that patients meet all of the requirements for being counted toward a facility's meeting the 60 percent rule requirements. As such, we believe that certain ICD–9–CM codes currently on the presumptive methodology list do not necessarily demonstrate a patient's meeting the requirements for inclusion in a facility's 60 percent compliance threshold, and, as such, should be removed from the list to better reflect the regulations.

Therefore, we performed a clinical analysis of the ICD–9–CM code list to determine the clinical appropriateness of each individual ICD–9–CM code's inclusion on the list, and a statistical analysis of the ICD–9–CM diagnoses code list to enhance our understanding of how individual ICD–9–CM codes are being used by IRFs. Based on these analyses, we are proposing specific revisions to the ICD–9–CM code list that are described below in sections VII.B.1 through VII.B.6 of this proposed rule.

We encourage stakeholders comment on the following proposals. All such public comment(s) will be addressed in the final rule.

1. Non-Specific Diagnosis Codes

We believe that highly descriptive codes provide the best and clearest way to ensure the appropriateness of a given patient's inclusion in the presumptive method of calculating a facility's compliance percentage. Therefore, whenever possible, we believe that the most specific code that describes a medical disease, condition, or injury should be documented on the IRF–PAI. Generally, ''unspecified'' codes are used when there is lack of information about location or severity of medical conditions in the medical record. However, site and/or severity of condition is an important determinant in assessing whether a patient's principal or secondary diagnosis falls into the 13 qualifying conditions and, as such, should count toward the facility's compliance with the 60 percent rule. For this reason, and in accordance with ICD–9–CM coding guidelines, we believe that specific diagnosis codes that narrowly identify anatomical sites where disease, injury, or condition exist should be required when coding patients' conditions on the IRF–PAI whenever such codes are available. Furthermore, on the same note, we believe that one should also include on the IRF–PAI the more descriptive ICD–9–CM code that indicates the degree of injury in instances of burns. In accordance with these principles, we propose to remove non-specific codes from Appendix C whenever more specific codes are available as 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 compliance percentage. 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.

For example, the current ICD–9–CM codes 820.8 ''Unspecified part of neck of femur, closed'' and 820.9 ''Unspecified part of neck of femur, open'', which indicate hip fractures, could be replaced with more specific codes (820.01–820.09, 820.11–820.19, 820.21–820.22, or 820.31–820.32). We believe that the proposed removal of the unspecified codes listed in Table 7, ''Proposed ICD–9–CM Codes To Be Removed From the Appendix C: ICD–9–CM Codes That Meet Presumptive Compliance Criteria,'' would not negatively impact a provider's ability to meet the compliance percentage threshold because these diagnoses could be coded under the aforementioned more specific codes. More specific codes will aid us in determining (by the nature of the site, severity, degree of injury, etc.) whether a patient's principal or secondary diagnosis falls into the 13 qualifying conditions and should count toward the 60 percent rule.

2. Arthritis Codes

Our analysis of the list of ICD–9–CM codes that are currently deemed to meet the 60 percent rule required us to reexamine the overall application of the compliance criteria in regards to the arthritis codes. Utilization patterns for the arthritis codes indicated that some of the codes in this category are coded far more frequently than we had anticipated, given the severity and prior treatment requirements outlined in regulation. When we adopted the arthritis conditions in the FY 2004 final rule (69 FR 25752), we did so because we believed that these conditions were appropriate for treatment in an IRF. However, we limited the arthritis conditions to those that were sufficiently severe and in which

intensive inpatient rehabilitation would be an appropriate modality of treatment. We anticipated that less severe arthritic conditions could be satisfactorily managed outside of IRFs since these cases would not require the intensive therapy provided in the inpatient rehabilitation setting. Likewise, we expected that even in cases where patients with arthritis conditions severe enough to require intensive inpatient rehabilitation, some patients would improve after an appropriate, aggressive, and sustained course of treatment in an outpatient setting. ''An appropriated, aggressive, and sustained course of treatment in an outpatient setting'' is defined in Chapter 3, section 140.1.1.C of the Medicare Claims Processing Manual (Pub. 100–04). We believe that there may be arthritis ICD–9–CM codes entered on the IRF–PAI for cases that do not meet the severity and prior treatment requirements outlined in regulation. Thus, after reexamining our application of the compliance criteria in regards to the arthritis codes, we determined that factors beyond the ICD–9–CM code should be reviewed to establish whether these IRF patients should be included in the IRF's compliance percentage.

In the regulations at § 412.29(b)(2)(x) through § 412.29(b)(2)(xii), we describe 3 medical conditions that, if present, make a patient eligible for inclusion in the calculation of the compliance percentage if additional circumstances are met. The 3 medical conditions are as follows:

- Active, polyarticular rheumatoid arthritis, psoriatic arthritis, and seronegative arthropathies resulting in significant functional impairment of ambulation and other activities of daily living that have 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 that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.
- Systemic vasculidities with joint inflammation, resulting in significant functional impairment of ambulation and other activities of daily living that have 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 that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.
- Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease) involving two or more major weight bearing joints (elbow, shoulders, hips, or knees, but not counting a joint with a prosthesis) with joint deformity and substantial loss of range of motion, atrophy of muscles surrounding the joint, significant functional impairment of ambulation and other activities of daily living that have not improved after the patient has participated in 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 have the potential to improve with more intensive rehabilitation. (A joint replaced by a prosthesis no longer is considered to have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.)

As stated above, the inclusion of patients with these medical conditions in the compliance percentage is conditioned on those patients meeting certain 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 whether or not these additional eligibility requirements were met. We believe that a qualitative assessment (such as a medical review) is necessary to determine if the medical record would support inclusion of individuals with the arthritis and arthropathy conditions outlined in our regulations at § 412.29(b)(2)(x) through § 412.29(b)(2)(xii) in a facility's compliance percentage. Thus, we propose to remove the ICD–9–CM diagnosis codes associated with the medical conditions outlined in our regulations at § 412.29(b)(2)(x) through § 412.29(b)(2)(xii) from the presumptive method ICD–9–CM code list in Appendix C.

We expect that the FI/MAC will be able, upon medical review, to include those patients in a facility's 60 percent rule compliance percentage in accordance with chapter 3, § 140.1.4 of the Medicare Claims Processing Manual (Pub. 100–04) after it has confirmed the severity and prior treatment requirements. So IRFs will continue to be able to include these individuals in their compliance percentages. In Table 7, we list the ICD–9–CM codes associated with the medical conditions listed at § 412.29(b)(2)(x) through § 412.29(b)(2)(xii) that we propose to remove from Appendix C.

3. Some Congenital Anomaly Diagnosis Codes

Though congenital deformity is one of the 13 medical conditions that may generally qualify for inclusion in the presumptive method for calculating compliance with the 60 percent rule, we find that some of the specific ICD–9–CM diagnosis codes in Appendix C for congenital anomalies represent such serious conditions that a patient with one of these conditions would be unlikely to be able to meaningfully participate in an intensive rehabilitation therapy program. For example, Craniorachischisis (ICD–9–CM code 740.1) is a congenital malformation where the neural tube from the midbrain down to the upper sacral region of the spinal cord remains open. The neural tube is the embryo's precursor to the central nervous system, which comprises the brain and spinal cord. Similarly, Iniencephaly (ICD–9–CD code 740.2) is a congenital malformation in which parts of the brain do not form and the patient does not have a neck. If a patient with one of these conditions were able to participate in the intensive rehabilitation services provided in an IRF, then the FI/MAC would be able to count that case toward an IRF's 60 percent rule compliance calculation upon medical review. However, because beneficiaries with these diagnoses likely would not be able to actively participate in an intensive rehabilitation program, we do not believe that we can presumptively include such cases in an IRF's compliance percentage. Thus, we propose to remove these congenital deformity codes, and others like them, from Appendix C. All of the congenital anomaly diagnosis codes that we propose to remove from appendix C are listed in Table 7.

4. Unilateral Upper Extremity Amputations Diagnosis Codes

Though amputation is generally one of the 13 medical conditions that qualify for inclusion in the presumptive method for calculating compliance with the 60 percent rule, we propose the removal of certain ICD–9–CM codes for unilateral upper extremity amputations from Appendix C because we believe 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 qualify for treatment in an IRF. Some patients with upper extremity amputations 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 unilateral upper extremity amputations 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 the unilateral upper extremity amputation, 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 a unilateral upper extremity amputation ICD–9–CM code. If the patient has comorbidities that would necessitate treatment in an IRF, then those comorbidities could qualify the patient for inclusion in the presumptive method of calculating compliance with the 60 percent rule requirements. If the codes for such a patient's comorbidities do not appear in Appendix C, they could be found on medical review to meet the criteria for inclusion in the IRF's 60 percent rule compliance rate. Thus, we propose to remove the unilateral upper extremity amputation ICD–9–CM codes listed in Table 7.

5. Miscellaneous Diagnosis Codes That Do Not Require Intensive Rehabilitation Services For Treatment

We have identified additional ICD–9–CM diagnosis codes in Appendix C that should not be included in the listing because as single conditions, they do not serve as an indication of a patient qualifying for inclusion in an IRF's compliance percentage under the presumptive method for calculating compliance with the 60 percent rule. These patients generally do not require intensive rehabilitation services or cannot be shown to have undergone appropriate diagnostic testing based on the ICD–9–CM code alone. For the reasons discussed below, we propose to remove the following ICD–9–CM codes from Appendix C. (These ICD–9–CM codes are also listed in Table 7):

• *Tuberculous (abscess, meningitis, and encephalitis or myelitis) and Tuberculoma (of the meninges, brain, or spinal cord) where a bacterial or histological examination was not done (see Table 7 for specific codes)*—Appropriate patient care dictates that the IRF physician must document the means by which the organism, whether it be bacteriologic or histologic, was tested. We are proposing to remove these codes from the list in Appendix C because the subclassification indicates that a bacteriologic or histologic examination has not been performed.

• *Postherpetic polyneuropathy* (053.13)—This is a condition characterized by severe pain, which typically requires pain medication or other pain control therapies but does not typically require the intensive inpatient rehabilitation services of an IRF. In fact, the prescriptive hands-on therapeutic interventions provided in an IRF could exacerbate the patient's pain. For these reasons, we are proposing to remove this code from Appendix C.

• *Louping ill* (063.1)—This ICD–9–CM code refers to an acute viral disease primarily of sheep that is not endemic to the United States. Louping ill disease has been recognized in Scotland for centuries, but only 39 cases of human infection have been described and none of these cases have been observed in the United States. Louping ill is a disease which has many manifestations, not all requiring inpatient rehabilitation hospital services. We believe that the ICD–9–CM code for this diagnosis does not provide the information necessary for us to determine presumptively if the patient should count toward the IRF's compliance threshold. However, as with all of the codes that we are proposing to remove from appendix C, if someone with this diagnosis were to be admitted to an IRF, where appropriate, it could be found by an FI/MAC to meet the 60 percent rule requirements on medical review.

• *Brain death* (348.82)—We believe that it is unlikely that a patient with this condition would require the intensive inpatient rehabilitation services provided in an IRF. For this reason, we propose to remove this code from Appendix C.

• *Myasthenia gravis without (acute) exacerbation* (358.00)—Although we believe that a patient experiencing an acute attack of Myasthenia Gravis could potentially require the services of an IRF (see ICD–9 code 358.01 ''Myasthenia gravis with (acute) exacerbation''), the ICD–9–CM code that we propose to remove from appendix C is used for patients who are not experiencing an acute exacerbation of the condition and most likely do not require the intensive inpatient rehabilitation services provided in an IRF.

• *Other specified myotonic disorder* (359.29)—Myotonia fluctuans, myotonia permanens, and paramyotonia congenital reflect conditions that are exacerbated by exercise. Therefore, these conditions would not likely require the intensive inpatient rehabilitation services of an IRF. Therefore, we are proposing to remove it from the list in appendix C.

• *Periodic paralysis* (359.3)—The treatment for periodic paralysis involves pharmaceutical interventions and lifestyle changes that control exercise and activity, but patients with this condition do not generally require the intensive inpatient rehabilitation services of an IRF. In fact, it is unclear how the intensive inpatient rehabilitation services provided in an IRF would effectively treat this condition. Thus, we propose to remove this code from the list in Appendix C.

• *Brachial plexus lesions* (353.0)—Care and treatment for this condition affecting an upper extremity do not typically require close medical supervision by a physician or weekly interdisciplinary team meetings to reach the patient's goals. Thus, patients with this condition do not typically require the intensive inpatient rehabilitation services provided in an IRF. Therefore, we propose to remove this code from the list in appendix C.

• *Neuralgic amyothrophy* (353.5)—This condition is also known as Parsonage-Turner syndrome or brachial plexus neuritis. It is a distinct peripheral nervous system disorder characterized by attacks of extreme neuropathic pain and rapid multifocal weakness and atrophy in the upper limbs. Patients with this condition do not typically require close medical supervision by a physician or weekly interdisciplinary team meetings to reach the patient's therapy goals. Thus, patients with this condition do not typically require the intensive inpatient rehabilitation services provided in an IRF. Therefore, we propose to remove this code from the list Appendix C.

• *Other nerve root and plexus disorders* (353.8)—More descriptive codes provide the clearest way to ensure the appropriateness of a patient's inclusion in the compliance percentage. For example, Lumbosacral plexus lesions (353.1) could substitute for Other nerve root and plexus disorders (353.8). Thus, patients with this condition do not typically require the intensive inpatient rehabilitation services provided in an IRF. Therefore, we propose to remove this code from the list in Appendix C.

6. Additional Diagnosis Codes

During our review of the diagnosis codes that meet the 60 percent compliance criteria, we did not identify any ICD–9–CM codes that would be appropriate to add to the list. However, we welcome public comment regarding ICD–9–CM diagnosis codes that are not currently on the presumptive

methodology list of codes that stakeholders believe should be added to the list and that specifically identify one of the conditions listed at § 412.29(b)(2), that require intensive inpatient rehabilitation, and can be presumptively identified by a ICD–9–CM code.

TABLE 7—PROPOSED ICD–9–CM CODES TO BE REMOVED FROM APPENDIX C: ICD–9–CM CODES THAT MEET PRESUMPTIVE COMPLIANCE CRITERIA

ICD–9–CM Code	Diagnosis
013.00	Tuberculous meningitis, unspecified.
013.01	Tuberculous meningitis, bacteriological or histological examination not done.
013.10	Tuberculoma of meninges, unspecified.
013.11	Tuberculoma of meninges, bacteriological or histological examination not done.
013.20	Tuberculoma of brain, unspecified.
013.21	Tuberculoma of brain, bacteriological or histological examination not done.
013.30	Tuberculous abscess of brain, unspecified.
013.31	Tuberculous abscess of brain, bacteriological or histological examination not done.
013.40	Tuberculoma of spinal cord, unspecified.
013.41	Tuberculoma of spinal cord, bacteriological or histological examination not done.
013.50	Tuberculous abscess of spinal cord, unspecified.
013.51	Tuberculous abscess of spinal cord, bacteriological or histological examination not done.
013.60	Tuberculous encephalitis or myelitis, unspecified.
013.61	Tuberculous encephalitis or myelitis, bacteriological or histological examination not done.
047.9	Unspecified viral meningitis.
049.9	Unspecified non-arthropod-borne viral diseases of central nervous system.
053.13	Postherpetic polyneuropathy.
062.9	Mosquito-borne viral encephalitis, unspecified.
063.1	Louping ill.
063.9	Tick-borne viral encephalitis, unspecified.
320.9	Meningitis due to unspecified bacterium.
322.9	Meningitis, unspecified.
323.9	Unspecified causes of encephalitis, myelitis, and encephalomyelitis.
324.9	Intracranial and intraspinal abscess of unspecified site.
335.10	Spinal muscular atrophy, unspecified.
335.9	Anterior horn cell disease, unspecified.
336.9	Unspecified disease of spinal cord.
341.9	Demyelinating disease of central nervous system, unspecified.
342.00	Flaccid hemiplegia and hemiparesis affecting unspecified side.
342.10	Spastic hemiplegia and hemiparesis affecting unspecified side.
342.80	Other specified hemiplegia and hemiparesis affecting unspecified side.
342.90	Hemiplegia, unspecified, affecting unspecified side.
342.91	Hemiplegia, unspecified, affecting dominant side.
342.92	Hemiplegia, unspecified, affecting nondominant side.
343.3	Congenital monoplegia.
343.9	Infantile cerebral palsy, unspecified.
344.00	Quadriplegia, unspecified.
344.5	Unspecified monoplegia.
348.82	Brain death.
353.0	Brachial plexus lesions.
353.2	Cervical root lesions, not elsewhere classified.
353.3	Thoracic root lesions, not elsewhere classified.
353.4	Lumbosacral root lesions, not elsewhere classified.
353.5	Neuralgic amyotrophy.
353.8	Other nerve root and plexus disorders.
354.5	Mononeuritis multiplex.
356.9	Unspecified hereditary and idiopathic peripheral neuropathy.
358.00	Myasthenia gravis without (acute) exacerbation.
359.29	Other specified myotonic disorder.
359.3	Periodic paralysis.
432.9	Unspecified intracranial hemorrhage.
438.20	Late effects of cerebrovascular disease, hemiplegia affecting unspecified side.
438.30	Late effects of cerebrovascular disease, monoplegia of upper limb affecting unspecified side.
438.31	Late effects of cerebrovascular disease, monoplegia of upper limb affecting dominant side.
438.32	Late effects of cerebrovascular disease, monoplegia of upper limb affecting nondominant side.
438.40	Late effects of cerebrovascular disease, monoplegia of lower limb affecting unspecified side.
438.50	Late effects of cerebrovascular disease, other paralytic syndrome affecting unspecified side.
433.91	Occlusion and stenosis of unspecified precerebral artery with cerebral infarction.
434.91	Cerebral artery occlusion, unspecified with cerebral infarction.
446.0	Polyarteritis nodosa.
711.20	Arthropathy in Behcet's syndrome, site unspecified.
711.21	Arthropathy in Behcet's syndrome, shoulder region.
711.22	Arthropathy in Behcet's syndrome, upper arm.
711.23	Arthropathy in Behcet's syndrome, forearm.
711.24	Arthropathy in Behcet's syndrome, hand.
711.25	Arthropathy in Behcet's syndrome, pelvic region and thigh.

TABLE 7—PROPOSED ICD–9–CM CODES TO BE REMOVED FROM APPENDIX C: ICD–9–CM CODES THAT MEET PRESUMPTIVE COMPLIANCE CRITERIA—Continued

ICD–9–CM Code	Diagnosis
711.26	Arthropathy in Behcet's syndrome, lower leg.
711.27	Arthropathy in Behcet's syndrome, ankle and foot.
711.28	Arthropathy in Behcet's syndrome, other specified sites.
711.29	Arthropathy in Behcet's syndrome, multiple sites.
713.0	Arthropathy associated with other endocrine and metabolic disorders.
713.1	Arthropathy associated with gastrointestinal conditions other than infections.
713.2	Arthropathy associated with hematological disorders.
713.3	Arthropathy associated with dermatological disorders.
713.4	Arthropathy associated with respiratory disorders.
713.6	Arthropathy associated with hypersensitivity reaction.
713.7	Other general diseases with articular involvement.
714.0	Rheumatoid arthritis.
714.1	Felty's syndrome.
714.2	Other rheumatoid arthritis with visceral or systemic involvement.
714.32	Pauciarticular juvenile rheumatoid arthritis.
714.81	Rheumatoid lung.
714.89	Other specified inflammatory polyarthropathies.
714.9	Unspecified inflammatory polyarthropathy.
715.11	Osteoarthrosis, localized, primary, shoulder region.
715.12	Osteoarthrosis, localized, primary, upper arm.
715.15	Osteoarthrosis, localized, primary, pelvic region and thigh.
715.16	Osteoarthrosis, localized, primary, lower leg.
715.21	Osteoarthrosis, localized, secondary, shoulder region.
715.22	Osteoarthrosis, localized, secondary, upper arm.
715.25	Osteoarthrosis, localized, secondary, pelvic region and thigh.
715.26	Osteoarthrosis, localized, secondary, lower leg.
715.31	Osteoarthrosis, localized, not specified whether primary or secondary, shoulder region.
715.32	Osteoarthrosis, localized, not specified whether primary or secondary, upper arm.
715.35	Osteoarthrosis, localized, not specified whether primary or secondary, pelvic region and thigh.
715.36	Osteoarthrosis, localized, not specified whether primary or secondary, lower leg.
716.01	Kaschin-Beck disease, shoulder region.
716.02	Kaschin-Beck disease, upper arm.
716.05	Kaschin-Beck disease, pelvic region and thigh.
716.06	Kaschin-Beck disease, lower leg.
716.11	Traumatic arthropathy, shoulder region.
716.12	Traumatic arthropathy, upper arm.
716.15	Traumatic arthropathy, pelvic region and thigh.
716.16	Traumatic arthropathy, lower leg.
716.21	Allergic arthritis, shoulder region.
716.22	Allergic arthritis, upper arm.
716.25	Allergic arthritis, pelvic region and thigh.
716.26	Allergic arthritis, lower leg.
716.51	Unspecified polyarthropathy or polyarthritis, shoulder region.
716.52	Unspecified polyarthropathy or polyarthritis, upper arm.
716.55	Unspecified polyarthropathy or polyarthritis, pelvic region and thigh.
716.56	Unspecified polyarthropathy or polyarthritis, lower leg.
719.30	Palindromic rheumatism, site unspecified.
719.31	Palindromic rheumatism, shoulder region.
719.32	Palindromic rheumatism, upper arm.
719.33	Palindromic rheumatism, forearm.
719.34	Palindromic rheumatism, hand.
719.35	Palindromic rheumatism, pelvic region and thigh.
719.36	Palindromic rheumatism, lower leg.
719.37	Palindromic rheumatism, ankle and foot.
719.38	Palindromic rheumatism, other specified sites.
719.39	Palindromic rheumatism, multiple sites.
720.0	Ankylosing spondylitis.
720.81	Inflammatory spondylopathies in diseases classified elsewhere.
720.89	Other inflammatory spondylopathies.
721.91	Spondylosis of unspecified site, with myelopathy.
722.70	Intervertebral disc disorder with myelopathy, unspecified region.
740.1	Craniorachischisis.
740.2	Iniencephaly.
741.00	Spina bifida with hydrocephalus, unspecified region.
741.90	Spina bifida without mention of hydrocephalus, unspecified region.
742.1	Microcephalus.
754.30	Congenital dislocation of hip, unilateral.
754.31	Congenital dislocation of hip, bilateral.
754.32	Congenital subluxation of hip, unilateral.
755.20	Unspecified reduction deformity of upper limb.

TABLE 7—PROPOSED ICD–9–CM CODES TO BE REMOVED FROM APPENDIX C: ICD–9–CM CODES THAT MEET PRESUMPTIVE COMPLIANCE CRITERIA—Continued

ICD–9–CM Code	Diagnosis
755.21	Transverse deficiency of upper limb.
755.22	Longitudinal deficiency of upper limb, not elsewhere classified.
755.23	Longitudinal deficiency, combined, involving humerus, radius, and ulna (complete or incomplete).
755.24	Longitudinal deficiency, humeral, complete or partial (with or without distal deficiencies, incomplete).
755.25	Longitudinal deficiency, radioulnar, complete or partial (with or without distal deficiencies, incomplete).
755.26	Longitudinal deficiency, radial, complete or partial (with or without distal deficiencies, incomplete).
755.27	Longitudinal deficiency, ulnar, complete or partial (with or without distal deficiencies, incomplete).
755.28	Longitudinal deficiency, carpals or metacarpals, complete or partial (with or without incomplete phalangeal deficiency).
755.30	Unspecified reduction deformity of lower limb.
755.4	Reduction deformities, unspecified limb.
755.51	Congenital deformity of clavicle.
755.53	Radioulnar synostosis.
755.61	Coxa valga, congenital.
755.62	Coxa vara, congenital.
755.63	Other congenital deformity of hip (joint).
756.50	Congenital osteodystrophy, unspecified.
800.00	Closed fracture of vault of skull without mention of intracranial injury, unspecified state of consciousness.
800.09	Closed fracture of vault of skull without mention of intracranial injury, with concussion, unspecified.
800.10	Closed fracture of vault of skull with cerebral laceration and contusion, unspecified state of consciousness.
800.19	Closed fracture of vault of skull with cerebral laceration and contusion, with concussion, unspecified.
800.20	Closed fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness.
800.29	Closed fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, with concussion, unspecified.
800.30	Closed fracture of vault of skull with other and unspecified intracranial hemorrhage, unspecified state of consciousness.
800.39	Closed fracture of vault of skull with other and unspecified intracranial hemorrhage, with concussion, unspecified.
800.40	Closed fracture of vault of skull with intracranial injury of other and unspecified nature, unspecified state of consciousness.
800.49	Closed fracture of vault of skull with intracranial injury of other and unspecified nature, with concussion, unspecified.
800.50	Open fracture of vault of skull without mention of intracranial injury, unspecified state of consciousness.
800.59	Open fracture of vault of skull without mention of intracranial injury, with concussion, unspecified.
800.60	Open fracture of vault of skull with cerebral laceration and contusion, unspecified state of consciousness.
800.69	Open fracture of vault of skull with cerebral laceration and contusion, with concussion, unspecified.
800.70	Open fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness.
800.79	Open fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, with concussion, unspecified.
800.80	Open fracture of vault of skull with other and unspecified intracranial hemorrhage, unspecified state of consciousness.
800.89	Open fracture of vault of skull with other and unspecified intracranial hemorrhage, with concussion, unspecified.
800.90	Open fracture of vault of skull with intracranial injury of other and unspecified nature, unspecified state of consciousness.
800.99	Open fracture of vault of skull with intracranial injury of other and unspecified nature, with concussion, unspecified.
801.00	Closed fracture of base of skull without mention of intracranial injury, unspecified state of consciousness.
801.09	Closed fracture of base of skull without mention of intracranial injury, with concussion, unspecified.
801.10	Closed fracture of base of skull with cerebral laceration and contusion, unspecified state of consciousness.
801.19	Closed fracture of base of skull with cerebral laceration and contusion, with concussion, unspecified.
801.20	Closed fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness.
801.29	Closed fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, with concussion, unspecified.
801.30	Closed fracture of base of skull with other and unspecified intracranial hemorrhage, unspecified state of consciousness.
801.39	Closed fracture of base of skull with other and unspecified intracranial hemorrhage, with concussion, unspecified.
801.40	Closed fracture of base of skull with intracranial injury of other and unspecified nature, unspecified state of consciousness.
801.49	Closed fracture of base of skull with intracranial injury of other and unspecified nature, with concussion, unspecified.
801.50	Open fracture of base of skull without mention of intracranial injury, unspecified state of consciousness.
801.59	Open fracture of base of skull without mention of intracranial injury, with concussion, unspecified.
801.60	Open fracture of base of skull with cerebral laceration and contusion, unspecified state of consciousness.
801.69	Open fracture of base of skull with cerebral laceration and contusion, with concussion, unspecified.
801.70	Open fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness.
801.79	Open fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, with concussion, unspecified.
801.80	Open fracture of base of skull with other and unspecified intracranial hemorrhage, unspecified state of consciousness.
801.89	Open fracture of base of skull with other and unspecified intracranial hemorrhage, with concussion, unspecified.
801.90	Open fracture of base of skull with intracranial injury of other and unspecified nature, unspecified state of consciousness.
801.99	Open fracture of base of skull with intracranial injury of other and unspecified nature, with concussion, unspecified.
803.00	Other closed skull fracture without mention of intracranial injury, unspecified state of consciousness.
803.09	Other closed skull fracture without mention of intracranial injury, with concussion, unspecified.
803.10	Other closed skull fracture with cerebral laceration and contusion, unspecified state of consciousness.
803.19	Other closed skull fracture with cerebral laceration and contusion, with concussion, unspecified.
803.20	Other closed skull fracture with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness.
803.29	Other closed skull fracture with subarachnoid, subdural, and extradural hemorrhage, with concussion, unspecified.
803.30	Other closed skull fracture with other and unspecified intracranial hemorrhage, unspecified state of unconsciousness.
803.39	Other closed skull fracture with other and unspecified intracranial hemorrhage, with concussion, unspecified.
803.40	Other closed skull fracture with intracranial injury of other and unspecified nature, unspecified state of consciousness.
803.49	Other closed skull fracture with intracranial injury of other and unspecified nature, with concussion, unspecified.
803.50	Other open skull fracture without mention of injury, unspecified state of consciousness.
803.59	Other open skull fracture without mention of intracranial injury, with concussion, unspecified.
803.60	Other open skull fracture with cerebral laceration and contusion, unspecified state of consciousness.
803.69	Other open skull fracture with cerebral laceration and contusion, with concussion, unspecified.

TABLE 7—PROPOSED ICD–9–CM CODES TO BE REMOVED FROM APPENDIX C: ICD–9–CM CODES THAT MEET PRESUMPTIVE COMPLIANCE CRITERIA—Continued

ICD–9–CM Code	Diagnosis
803.70	Other open skull fracture with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness.
803.79	Other open skull fracture with subarachnoid, subdural, and extradural hemorrhage, with concussion, unspecified.
803.80	Other open skull fracture with other and unspecified intracranial hemorrhage, unspecified state of consciousness.
803.89	Other open skull fracture with other and unspecified intracranial hemorrhage, with concussion, unspecified.
803.90	Other open skull fracture with intracranial injury of other and unspecified nature, unspecified state of consciousness.
803.99	Other open skull fracture with intracranial injury of other and unspecified nature, with concussion, unspecified.
804.00	Closed fractures involving skull or face with other bones, without mention of intracranial injury, unspecified state of consciousness.
804.09	Closed fractures involving skull of face with other bones, without mention of intracranial injury, with concussion, unspecified.
804.10	Closed fractures involving skull or face with other bones, with cerebral laceration and contusion, unspecified state of consciousness.
804.19	Closed fractures involving skull or face with other bones, with cerebral laceration and contusion, with concussion, unspecified.
804.20	Closed fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness.
804.29	Closed fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, with concussion, unspecified.
804.30	Closed fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, unspecified state of consciousness.
804.39	Closed fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, with concussion, unspecified.
804.40	Closed fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, unspecified state of consciousness.
804.49	Closed fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, with concussion, unspecified.
804.60	Open fractures involving skull or face with other bones, with cerebral laceration and contusion, unspecified state of consciousness.
804.69	Open fractures involving skull or face with other bones, with cerebral laceration and contusion, with concussion, unspecified.
804.70	Open fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness.
804.79	Open fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, with concussion, unspecified.
804.80	Open fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, unspecified state of consciousness.
804.89	Open fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, with concussion, unspecified.
804.90	Open fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, unspecified state of consciousness.
804.99	Open fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, with concussion, unspecified.
806.00	Closed fracture of C1–C4 level with unspecified spinal cord injury.
806.05	Closed fracture of C5–C7 level with unspecified spinal cord injury.
806.10	Open fracture of C1–C4 level with unspecified spinal cord injury.
806.15	Open fracture of C5–C7 level with unspecified spinal cord injury.
806.20	Closed fracture of T1–T6 level with unspecified spinal cord injury.
806.25	Closed fracture of T7–T12 level with unspecified spinal cord injury.
806.30	Open fracture of T1–T6 level with unspecified spinal cord injury.
806.35	Open fracture of T7–T12 level with unspecified spinal cord injury.
806.60	Closed fracture of sacrum and coccyx with unspecified spinal cord injury.
806.70	Open fracture of sacrum and coccyx with unspecified spinal cord injury.
820.00	Closed fracture of intracapsular section of neck of femur, unspecified.
820.10	Open fracture of intracapsular section of neck of femur, unspecified.
820.30	Open fracture of trochanteric section of neck of femur, unspecified.
820.8	Closed fracture of unspecified part of neck of femur.
820.9	Open fracture of unspecified part of neck of femur.
839.10	Open dislocation, cervical vertebra, unspecified.
850.5	Concussion with loss of consciousness of unspecified duration.
851.00	Cortex (cerebral) contusion without mention of open intracranial wound, unspecified state of consciousness.
851.09	Cortex (cerebral) contusion without mention of open intracranial wound, with concussion, unspecified.
851.10	Cortex (cerebral) contusion with open intracranial wound, unspecified state of consciousness.
851.19	Cortex (cerebral) contusion with open intracranial wound, with concussion, unspecified.
851.20	Cortex (cerebral) laceration without mention of open intracranial wound, unspecified state of consciousness.
851.29	Cortex (cerebral) laceration without mention of open intracranial wound, with concussion, unspecified.
851.30	Cortex (cerebral) laceration with open intracranial wound, unspecified state of consciousness.
851.39	Cortex (cerebral) laceration with open intracranial wound, with concussion, unspecified.
851.40	Cerebellar or brain stem contusion without mention of open intracranial wound, unspecified state of consciousness.
851.49	Cerebellar or brain stem contusion without mention of open intracranial wound, with concussion, unspecified.
851.50	Cerebellar or brain stem contusion with open intracranial wound, unspecified state of consciousness.
851.59	Cerebellar or brain stem contusion with open intracranial wound, with concussion, unspecified.
851.60	Cerebellar or brain stem laceration without mention of open intracranial wound, unspecified state of consciousness.
851.69	Cerebellar or brain stem laceration without mention of open intracranial wound, with concussion, unspecified.

TABLE 7—PROPOSED ICD–9–CM CODES TO BE REMOVED FROM APPENDIX C: ICD–9–CM CODES THAT MEET PRESUMPTIVE COMPLIANCE CRITERIA—Continued

ICD–9–CM Code	Diagnosis
851.70	Cerebellar or brain stem laceration with open intracranial wound, unspecified state of consciousness.
851.79	Cerebellar or brain stem laceration with open intracranial wound, with concussion, unspecified.
851.80	Other and unspecified cerebral laceration and contusion, without mention of open intracranial wound, unspecified state of consciousness.
851.89	Other and unspecified cerebral laceration and contusion, without mention of open intracranial wound, with concussion, unspecified.
851.90	Other and unspecified cerebral laceration and contusion, with open intracranial wound, unspecified state of consciousness.
851.99	Other and unspecified cerebral laceration and contusion, with open intracranial wound, with concussion, unspecified.
852.00	Subarachnoid hemorrhage following injury without mention of open intracranial wound, unspecified state of consciousness.
852.09	Subarachnoid hemorrhage following injury without mention of open intracranial wound, with concussion, unspecified.
852.10	Subarachnoid hemorrhage following injury with open intracranial wound, unspecified state of consciousness.
852.19	Subarachnoid hemorrhage following injury with open intracranial wound, with concussion, unspecified.
852.20	Subdural hemorrhage following injury without mention of open intracranial wound, unspecified state of consciousness.
852.29	Subdural hemorrhage following injury without mention of open intracranial wound, with concussion, unspecified.
852.30	Subdural hemorrhage following injury with open intracranial wound, unspecified state of consciousness.
852.39	Subdural hemorrhage following injury with open intracranial wound, with concussion, unspecified.
852.40	Extradural hemorrhage following injury without mention of open intracranial wound, unspecified state of consciousness.
852.49	Extradural hemorrhage following injury without mention of open intracranial wound, with concussion, unspecified.
852.50	Extradural hemorrhage following injury with open intracranial wound, unspecified state of consciousness.
852.59	Extradural hemorrhage following injury with open intracranial wound, with concussion, unspecified.
853.00	Other and unspecified intracranial hemorrhage following injury without mention of open intracranial wound, unspecified state of consciousness.
853.09	Other and unspecified intracranial hemorrhage following injury without mention of open intracranial wound, with concussion, unspecified.
853.10	Other and unspecified intracranial hemorrhage following injury with open intracranial wound, unspecified state of consciousness.
853.19	Other and unspecified intracranial hemorrhage following injury with open intracranial wound, with concussion, unspecified.
854.00	Intracranial injury of other and unspecified nature without mention of open intracranial wound, unspecified state of consciousness.
854.09	Intracranial injury of other and unspecified nature without mention of open intracranial wound, with concussion, unspecified.
854.10	Intracranial injury of other and unspecified nature with open intracranial wound, unspecified state of consciousness.
854.19	Intracranial injury of other and unspecified nature with open intracranial wound, with concussion, unspecified.
887.0	Traumatic amputation of arm and hand (complete) (partial), unilateral, below elbow, without mention of complication.
887.1	Traumatic amputation of arm and hand (complete) (partial), unilateral, below elbow, complicated.
887.2	Traumatic amputation of arm and hand (complete) (partial), unilateral, at or above elbow, without mention of complication.
887.3	Traumatic amputation of arm and hand (complete) (partial), unilateral, at or above elbow, complicated.
887.4	Traumatic amputation of arm and hand (complete) (partial), unilateral, level not specified, without mention of complication.
887.5	Traumatic amputation of arm and hand (complete) (partial), unilateral, level not specified, complicated.
941.00	Burn of unspecified degree of face and head, unspecified site.
941.02	Burn of unspecified degree of eye (with other parts of face, head, and neck).
941.09	Burn of unspecified degree of multiple sites [except with eye] of face, head, and neck.
942.00	Burn of unspecified degree of trunk, unspecified site.
942.01	Burn of unspecified degree of breast.
942.02	Burn of unspecified degree of chest wall, excluding breast and nipple.
942.03	Burn of unspecified degree of abdominal wall.
942.04	Burn of unspecified degree of back [any part].
942.05	Burn of unspecified degree of genitalia.
942.09	Burn of unspecified degree of other and multiple sites of trunk.
943.00	Burn of unspecified degree of upper limb, except wrist and hand, unspecified site.
943.01	Burn of unspecified degree of forearm.
943.02	Burn of unspecified degree of elbow.
943.03	Burn of unspecified degree of upper arm.
943.04	Burn of unspecified degree of axilla.
943.05	Burn of unspecified degree of shoulder.
943.06	Burn of unspecified degree of scapular region.
943.09	Burn of unspecified degree of multiple sites of upper limb, except wrist and hand.
943.30	Full-thickness skin [third degree, not otherwise specified] of upper limb, unspecified site.
943.40	Deep necrosis of underlying tissues [deep third degree] without mention of loss of a body part, of upper limb, unspecified site.
943.50	Deep necrosis of underlying tissues [deep third degree] with loss of a body part, of upper limb, unspecified site.
944.30	Full-thickness skin loss [third degree, not otherwise specified] of hand, unspecified site.
944.40	Deep necrosis of underlying tissues [deep third degree] without mention of loss of a body part, hand, unspecified site.
944.50	Deep necrosis of underlying tissues [deep third degree] with loss of a body part, of hand, unspecified site.
945.00	Burn of unspecified degree of lower limb [leg], unspecified site.
945.01	Burn of unspecified degree of toe(s) (nail).
945.02	Burn of unspecified degree of foot.
945.03	Burn of unspecified degree of ankle.
945.04	Burn of unspecified degree of lower leg.
945.05	Burn of unspecified degree of knee.
945.06	Burn of unspecified degree of thigh [any part].
945.09	Burn of unspecified degree of multiple sites of lower limb(s).

TABLE 7—PROPOSED ICD–9–CM CODES TO BE REMOVED FROM APPENDIX C: ICD–9–CM CODES THAT MEET PRESUMPTIVE COMPLIANCE CRITERIA—Continued

ICD–9–CM Code	Diagnosis
945.20	Blisters, epidermal loss [second degree] of lower limb [leg], unspecified site.
945.40	Deep necrosis of underlying tissues [deep third degree] without mention of loss of a body part, lower limb [leg], unspecified site.
945.50	Deep necrosis of underlying tissues [deep third degree] with loss of a body part, of lower limb [leg], unspecified site.
949.4	Deep necrosis of underlying tissue [deep third degree] without mention of loss of a body part, unspecified.
949.5	Deep necrosis of underlying tissues [deep third degree] with loss of a body part, unspecified.
997.60	Unspecified complication of amputation stump.

VIII. Proposed Non-Quality Related Revisions to IRF–PAI Sections

Under section 1886(j)(2)(D) of the Act, the Secretary is authorized to require rehabilitation facilities that provide inpatient hospital services to submit such data as the Secretary deems necessary to establish and administer the prospective payment system under subsection P. The collection of patient data is indispensable for the successful development and implementation of the IRF payment system. In the August 7, 2001 final rule, the inpatient rehabilitation facility patient assessment instrument (IRF–PAI) was adopted as the standardized patient assessment instrument under the IRF prospective payment system (PPS). The IRF–PAI was established for, and is still used to gather data to classify patients for payment under the IRF PPS. As discussed in section XII. of this proposed rule, it is also now used to collect certain data for the IRF Quality Reporting Program. IRFs are currently required to complete an IRF–PAI for every Medicare Part A, B or C patient who is admitted to, or discharged from an IRF.

Although there have been significant advancements in the industry, no IRF PPS payment-related changes have been made to the IRF–PAI form since its implementation—in FY 2002. We are proposing to amend certain response options, add additional data points, remove certain outdated items and change certain references to ensure that our policies reflect the current data needs of the IRF PPS program.

A. Proposed Updates

We propose to amend the response codes on the following items in the IRF–PAI:

- Item 15A: Admit From (Formerly item 15)
- Item 16A: Pre-Hospital Living Situation (Formerly item 16)
- Item 44D: Patient's Discharge Destination/Living Setting (Formerly item 44A)

To minimize possible confusion due to the use of different sets of status codes on the IRF–PAI and the CMS–1450 (also referred to as the UB–04) claim form, we believe that the IRF–PAI status codes should be changed to mirror those used on the CMS–1450 claim form. We believe this proposed update would help decrease the rate of coding errors on CMS–1450 claim forms. We believe this proposal would provide response options that mirror another commonly used instrument in the Medicare context allowing providers to use only one common set of response codes. We propose to amend the response options for the three items listed above to:

- 01—Home (private home/apt., board/care, assisted living, group home)
- 02—Short-term General Hospital
- 03—Skilled Nursing Facility (SNF)
- 50—Hospice
- 62—Another Inpatient Rehabilitation Facility
- 63—Long-Term Care Hospital (LTCH)
- 64—Medicaid Nursing Facility
- 65—Inpatient Psychiatric Facility
- 66—Critical Access Hospital
- 99—Not Listed

We also propose to update the options for responding to item 20B: Secondary Source. We find that the current response options for this data element exceed what we need to operate IRF PPS. Therefore, to decrease burden on IRFs through the implementation of simplified response options, we propose to limit secondary source response options to the following:

- 02—Medicare—Fee for Service
- 51—Medicare—Medicare Advantage
- 99—Not Listed

B. Proposed Additions

Further, we propose to add (or expand) the following items to the IRF–PAI:

- Item 25A: Height
- Item 26A: Weight
- Item 24: Comorbid Conditions (15 additional spaces)
- Item 44C: Was the patient discharged alive?
- Signature of Persons Completing the IRF–PAI

Items ''25A: Height'' and ''26A: Weight,'' are important items to collect for use in the classification of facilities for payment under the IRF–PPS as well as for the risk adjustment of quality measures (as described in section XII. of this proposed rule). In the regulations at § 412.29(b)(2), we specify a list of comorbid conditions that, if certain conditions are met, may qualify a patient for inclusion in an IRF's 60 percent rule compliance percentage. For example, a patient with a lower-extremity joint replacement comorbidity would qualify if the patient had a bilateral joint replacement, is over the age of 85, and/or has a BMI greater than 50. BMI is calculated using height and weight. As such, by adding a patients' height and weight information to the IRF–PAI we expect that the FI/MAC will be able, upon medical review, to include these patients in a facilities' 60 percent rule compliance percentage in accordance with chapter 3, § 140.14 of the Medicare Claims Processing Manual (Pub. 100.4), after it has confirmed any other severity and prior treatment requirements that may apply.

We also propose adding 15 additional spaces for providers to document patients' comorbid medical conditions at item 24: Comorbid Conditions (located in the medical information section of the IRF–PAI). The IRF–PAI currently has ten spaces available for providers to enter ICD codes for comorbid conditions. If finalized, the IRF–PAI would have a total of 25 spaces. Such expansion would support IRFs as they seek to code with greater specificity to support presumptive compliance percentage findings, and would be in keeping with recent industry-driven changes.

In response to the industry's request to update the claim form to allow for better accounting for patients comorbidities, added 15 additional spaces were added to the claim form for

providers to document ICD codes. We believe that the number of data elements allowed on the IRF–PAI should mirror the number allowed on the claim. Additionally, the ICD–10 coding scheme, which will be used beginning on October 1, 2014 is much more specific than the current ICD–9 coding. Therefore, when the agency moves from ICD–9 to ICD–10 coding, providers may need the additional spaces to code because of the greater specificity under ICD–10.

Furthermore, we propose to add a new item 44C: ''Was the patient discharged alive?'' to the discharge information section on the IRF–PAI. Adding this item as a standalone item would allow facilities that reply ''no'' to 44C to skip items 44D, 44E, and 45, which describe a living patient's discharge destination. This will reduce the burden on the time it takes to complete the IRF–PAI. Facilities that respond ''yes'' to item 44C will complete items 44D, 44E and 45 as they apply to the patient. We believe that adding this question as a standalone item would provide greater clarity for providers when documenting patient information on the IRF–PAI.

We propose adding a page to the IRF–PAI dedicated as the signature page for persons completing the IRF–PAI. As of the effective date of the IRF Coverage Requirements, see the August 7, 2009 FY 2010 IRF PPS final rule (74 FR 39762), the IRF–PAI forms must be maintained in the patient's medical record at the IRF (either in electronic or paper format), and information in the IRF–PAI must correspond with all of the information provided in the patient's IRF medical record. We received multiple public comments on the FY 2010 IRF PPS proposed rule regarding the requirement to include that IRF–PAI in the medical record questioning whether IRFs would need to adhere to the conditions of participation in § 482.24(c)(1) that require all patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures. When CMS responded (at *http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Downloads/IRF-Training-call_version_1.pdf*) that IRFs would need to adhere to § 482.24(c)(1), providers responded by asking for a place on the IRF–PAI where they would be able to document the required authentication. The proposed addition of a page for signatures of persons completing the IRF–PAI would fulfill providers' request to have an organized way to document who in the IRF has completed the assessment of the patient and when that assessment took place. We also believe that having a signature page for those completing the IRF–PAI will ensure that providers are satisfying both the IRF coverage requirements and the conditions of participation requirements.

C. Proposed Deletions

We propose to delete the following items from the IRF–PAI:

- Item 18: Pre-Hospital Vocational Category
- Item 19: Pre-Hospital Vocational Effort
- Item 25: Is patient comatose at admission?
- Item 26: Is patient delirious at admission?
- Item 28: Clinical signs of dehydration

We no longer believe that these items are necessary and in the interest of reducing burden on providers we would like to delete them.

Items 18: Pre-Hospital Vocational Category and 19: Pre-Hospital Vocational Effort (which are currently located in the admission identification section on the IRF–PAI) are not used for payment or quality purposes. While these items will, if finalized, be dropped from the IRF–PAI form, however, we would note that these data elements could be significant in a treatment context, in which case we would expect them to appear in the patient's medical record. For example, we believe that these data elements could be relevant during the care planning/discharge process as well as during interdisciplinary team meetings.

We also note, that items 25: Is patient comatose at admission, 26: Is patient delirious at admission, and 28: Clinical signs of dehydration (which are currently located in the medical information section on the IRF–PAI) are voluntary items that are not used for our payment or quality program purposes. Therefore, we do not believe it is necessary to collect this information on the IRF–PAI. Furthermore, to the extent such information would be relevant to the provision of patient care; this information should be captured in either the transfer documentation from the referring physician, or the patients' initial assessment documentation. As such, continuing to require this information on the IRF–PAI would be duplicative since the items should be well documented in the patients' medical record from their stay at the facility.

D. Proposed Changes

We are proposing to replace all references to the ICD–9–CM code(s) in the IRF–PAI with references to ICD code(s). This change would allow CMS to forgo making additional changes to the IRF–PAI when the adopted ICD code(s) change.

Proposed Technical Correction

We are proposing a technical correction at items 44D, 44E and 45 to conform to the additions proposed above. We believe that adding language to these items indicating that the question can be skipped depending upon how item 44C is answered, will help reduce submission errors for providers when filling out the IRF–PAI.

A draft of the IRF–PAI, with the proposed revisions discussed throughout this proposed rule is available for download on the IRF PPS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html*.

IX. Proposed Technical Corrections to the Regulations at § 412.130

In the FY 2012 IRF PPS final rule (76 FR 47869 through 47873), we revised the regulations for inpatient rehabilitation facilities at § 412.23(b), § 412.25(b), § 412.29, and § 412.30 to update and simplify the policies, to eliminate unnecessary repetition and confusion, and to enhance consistency with the IRF coverage requirements. Among other revisions, we removed the regulations that were formerly in § 412.30, and revised and consolidated the requirements regarding ''new'' IRFs and ''new'' IRF beds that previously existed in § 412.30 into the revised regulations at § 412.29(c). However, we have recently discovered that § 412.130, which outlines the policies regarding retroactive adjustments for incorrectly excluded hospitals and units, was not updated to reflect the changes to § 412.30 and § 412.29. Specifically, § 412.130 still references regulations in § 412.30 that were revised and consolidated into § 412.29(c). Further, it still references regulations that were formerly in § 412.23(b)(2), but were moved into § 412.29(b) in the FY 2012 IRF PPS final rule (76 FR 47869 through 47873).

Thus, in this proposed rule, we propose to make the following technical corrections to the regulations in § 412.130 to conform with the revisions to the regulations in § 412.23(b), § 412.29, and § 412.30 that were implemented in the FY 2012 IRF PPS final rule (76 FR 47869 through 47873):

- Replace the current reference to ''§ 412.23(b)(8)'' in § 412.130(a)(1) with the new reference to § 412.29(c),
- Replace all of the current references to ''§ 412.23(b)(2)'' in § 412.130(a)(1), (2), and (3) with the new reference to § 412.29(b),
- Replace the current reference to ''§ 412.30(a)'' in § 412.130(a)(2) with the new reference to § 412.29(c), and
- Replace the current reference to ''§ 412.30(c)'' in § 412.130(a)(3) with the new reference to § 412.29(c).

X. Proposed Revisions to the Conditions of Payment for IRF Units Under the IRF PPS

The regulations at § 412.25 specify the requirements for an IRF unit to be excluded from the inpatient prospective payment system (IPPS) specified in § 412.1(a)(1) and to instead be paid under the IRF PPS specified in § 412.1(a)(3). The requirements at § 412.25 are unique to IRF units of hospitals, whereas the requirements at § 412.29 apply to both freestanding IRF hospitals and IRF units of hospitals. Among the requirements at § 412.25 is the requirement (at § 412.25(a)(1)(iii)) that the institution of which the IRF unit is a part must have ''enough beds that are not excluded from the prospective payment systems to permit the provision of adequate cost information, as required by § 413.24(c) of this chapter.'' We have not previously specified how many such beds the hospital, of which the IRF unit is a part, must have to meet this requirement. However, we have recently received questions from providers about whether one or two hospital beds that are certified for payment under the IPPS, in some cases beds that are rarely used for patient care, would meet the requirement at § 412.25(a)(1)(iii). We believe this does not meet the requirement at § 412.25(a)(1)(iii), which provides for the hospital of which the IRF unit is a part to be an IPPS hospital, which we believe is not demonstrated by the presence of just one or two hospital beds.

Further, we are unclear how the IRF unit that is part of a hospital with only one or two beds would be able to meet another requirement, at § 412.25(a)(7), that specifies that an IRF unit must have beds that are ''physically separate from (that is, not commingled with) the hospital's other beds.'' The requirement at § 412.25(a)(7) means that there is some sort of physical separation (such as a different floor, a different wing, and different building, etc.) that separates the IRF unit from the rest of the hospital beds. We believe that it is unlikely that this requirement would be met in the situation in which the hospital of which the IRF unit is a part only has one or two beds, in some cases beds that are rarely used for patient care.

Thus, we propose to specify at § 412.25(a)(1)(iii) a minimum number of hospital beds that the IPPS hospital must have to meet the requirements at § 412.25(a)(1)(iii) for having an IRF unit. We note that, though § 412.25(a)(1)(iii) also applies to inpatient psychiatric facilities (IPFs), these facilities have their own requirements at § 412.27 for payment under the IPF PPS that we are not proposing to change in this proposed rule. IPFs should continue following the regulations at § 412.27.

We propose to specify in § 412.25(a)(1)(iii) that the institution of which the IRF unit is a part must have at least 10 staffed and maintained hospital beds that are not excluded from the IPPS, or at least 1 staffed and maintained hospital bed for every 10 certified IRF beds, whichever number is greater. If the institution is not able to meet this proposed requirement, then we propose that the IRF unit should instead be classified as an IRF hospital. We also propose to exclude CAHs that have IRF units from these requirements, as CAHs already have very specific bed size restrictions. We welcome stakeholder comments on the specific minimum hospital bed requirements for IRFs that we are proposing in this rule.

XI. Proposed Clarification of the Regulations at § 412.630

In the original rule establishing a prospective payment system for Medicare payment of inpatient hospital services provided by a rehabilitation hospital or by a rehabilitation unit of a hospital, we stated that that there would be no administrative or judicial review, under sections 1869 and 1878 of the Act or otherwise, of the establishment of case-mix groups, the methodology for the classification of patients within these groups, the weighting factors, the prospective payment rates, outlier and special payments and area wage adjustments. See 66 FR 41316, 41319 (August 7, 2001). Our intent was to honor the full breadth of the preclusion of administrative or judicial review provided by section 1886(j)(8) of the Act. However, the regulatory text reflecting the preclusion of review has been at times improperly interpreted to allow review of adjustments authorized under section 1886(j)(3)(v) of the Act. Because we interpret the preclusion of review at section 1886(j)(8) of the Act to apply to all payments authorized under section 1886(j)(3) of the Act, we do not believe that there should be administrative or judicial review of any part of the prospective rate. Accordingly, we are proposing to clarify our regulation at § 412.630 by deleting the word ''unadjusted'' so that the regulation would clearly preclude review of ''the Federal per discharge payment rates.'' This clarification will better conform the regulation to the statutory language.

As such, in accordance with sections 1886(j)(7)(A), (B), and (C) of the Act, we are proposing to revise the regulations at § 412.630 to clarify that administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, is prohibited with regard to the establishment of the methodology to classify a patient into the case-mix groups and the associated weighting factors, the federal per discharge payment rates, additional payments for outliers and special payments, and the area wage index.

XII. Proposed Revision to the Regulations at § 412.29

According to the regulations at § 412.29(d), to be excluded from the inpatient prospective payment system (IPPS) and instead be paid under the IRF PPS, a facility must ''have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital program. This procedure must ensure that the preadmission screening is reviewed and approved by a rehabilitation physician prior to the patient's admission to the IRF.'' The latter sentence of this regulation is based on the preadmission screening requirement for Medicare coverage of IRF services in § 412.622(a)(4)(i)(D). The requirement was repeated in both places for consistency.

However, in § 412.622(a)(4)(i)(D), we specify that this requirement applies to patients ''for whom the IRF seeks payment'' from Medicare. We believe that the analogous requirement in § 412.29(d) should also clearly state that it applies only to patients for whom the IRF is seeking payment directly from Medicare. Other payer sources, such as private insurance, have their own IRF admission requirements, and we do not believe that it would be appropriate to interfere with or duplicate the requirements that other payer sources may already have in place. Thus, we propose to amend § 412.29(d) to clarify that the IRF's preadmission screening procedure must ensure that the preadmission screening for a Medicare Part A fee-for-service patient is reviewed and approved by a

rehabilitation physician prior to the patient's admission to the IRF. We continue to believe that the basic preadmission screening procedure itself is an important element of providing quality IRF care to all patients and, thus, we propose to require that the basic preadmission screening procedure requirement remain in place for all patients regardless.

XIII. Proposed 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 IRF hospitals, IRF units that are affiliated with an acute care facility, and IRF units affiliated with a critical access hospital (CAH).

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 IRFs that fail 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 this subsection for a fiscal year being less than the 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 on 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.

We have generally adopted NQF-endorsed measures in our reporting programs. However, section 1886(j)(7)(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, so long as due consideration is given to measures that have been endorsed or adopted by a consensus-based organization identified by the Secretary.'' Under section 1886(j)(7)(D)(iii) of the Act, the Secretary was required to publish the selected measures that will be applicable to the FY 2014 IRF PPS no later than October 1, 2012.

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 and Currently in Use for the IRF Quality Reporting Program

1. Background

In the FY 2012 IRF PPS final rule, 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'' [1] (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 two 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 at a later date (76 FR 47874 through 47878).

In the CY 2013 OPPS/ASC proposed rule (77 FR 45193 through 45196), we proposed: (1) To adopt updates to the CAUTI measure that had been adopted by NQF after we had adopted an application of the prior version of the measure for the IRF QRP; (2) to adopt a policy that would allow any measure adopted for use in the IRF QRP to remain in effect until the measure was actively removed, suspended, or replaced (we also proposed to apply this proposal to the CAUTI and pressure ulcer measures that had already been adopted for use in the IRF QRP); and (3) to utilize a subregulatory process to incorporate NQF updates to IRF quality measure specifications that do not substantively change the nature of the measure. We also informed stakeholders that CMS had submitted an ad hoc request for NQF review of the pressure ulcer measure with a request to endorse the measure's use in two additional care settings—Long-Term Care Hospitals (LTCHs) and IRFs. Assuming that the review resulted in no substantive changes to the pressure ulcer measure, we noted that, if adopted, we would use the proposed subregulatory process to incorporate any NQF updates and revisions to the pressure ulcer measure specifications for the IRF QRP Program (77 FR 45196).

In the CY 2013 OPPS/ASC final rule (77 FR 68500 through 68507), we adopted the policies and measures as proposed, with one exception. At the time of the CY 2013 OPPS/ASC final rule, the NQF had endorsed the pressure ulcer measure for the IRF setting, and re-titled it to cover both residents and patients within LTCH and IRF settings, in addition to the Nursing Home/Skilled Nursing Facility setting. Although the 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). Public comments revealed that the ''Quality Indicator'' section of the IRF–PAI did not contain the data elements that would be needed to calculate a risk-adjusted measure. As a result, we decided to: (1) Adopt an application of NQF #0678 that was a

[1] The version of the CAUTI measure that was adopted in the FY 2012 IRF PPS final rule (76 FR 47874 through 47876) was titled ''Catheter-Associated Urinary Tract Infection [CAUTI] Rate Per 1,000 Urinary Catheter Days for ICU patients. However, shortly after the FY 2012 IRF PPS final rule was published, this measure was submitted by the CDC (measure steward) to the NQF for a measure maintenance review, The CDC asked for changes to the measure, including expansion of the scope of the measure to non-ICU patient care locations and additional healthcare facility settings, including IRFs. The name of the measure was changed to reflect the character of the revised CAUTI measure. This measure is now titled ''National Health Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure.''

non-risk-adjusted pressure ulcer measure (numerator and denominator data only); (2) collect the data required for the numerator and the denominator using the 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 NQF #0678, and then (4) adopt the NQF-endorsed version of the measure covering the IRF setting through rulemaking (77 FR 68507).

2. Previously Finalized IRF QRP Quality Measures

i. National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)

In the FY 2013 OPPS/ASC final rule we adopted the current version of NQF #0138 NHSN Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure (replacing an application of this measure which we initially adopted in the FY 2012 IRF PPS (76 FR 47874 through 47886)). The NQF endorsed measure applies to the FY 2015 IRF PPS annual increase factor and all subsequent payment determinations (77 FR 68504 through 68505).

Since the publication of the FY 2013 OPPS/ASC final rule, the NHSN CAUTI measure has not changed. Furthermore, we have not removed, suspended, or replaced this measure 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 NHSN can be found at the NHSN Web site at *http://www.cdc.gov/nhsn/inpatient-rehab/index.html*.

ii. Application of Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (short-stay) (NQF #0678)

In the CY 2103 OPPS/ASC final rule (77 FR 68500 through 68507) we finalized adoption of a non-risk-adjusted application of this measure using the current version of the IRF–PAI. We also stated that we would not begin public reporting of this measure until we had adopted the NQF-endorsed version of this measure. To adopt the NQF-endorsed version of this measure, we had to update the existing IRF–PAI to include the additional data elements necessary to risk adjust this measure. We also delayed public reporting of pressure ulcer measure results until we could use notice and comment rulemaking to amend the IRF–PAI to add the data elements necessary for risk adjusting NQF #0678 (77 FR 68507). We are not proposing any changes to the application of measure #0678 finalized in the FY 2013 OPPS/ASC final rule for the FY 2015 and FY 2016 IRF PPS annual increase factor. Furthermore, we have not removed, suspended, or replaced this measure and it remains an active part of the IRF QRP. Additional information about this measure can be found at *http://www.qualityforum.org/QPS/0678*. Our procedures for data submission for this measure also have remained the same. IRFs should continue to collect and submit pressure ulcer measure data during CY 2013 using the IRF–PAI released on October 1, 2012 for the FY 2015 IRF PPS annual increase factor. Further, IRFs should continue to collect and submit pressure ulcer measure data during the first three quarters of CY 2014 using the IRF–PAI released on October 1, 2012 for the FY 2016 IRF PPS annual increase factor.

However, we propose to adopt a revised version of the IRF–PAI starting October 1, 2014. This revised version of the IRF–PAI would allow collection of data elements necessary for risk adjustment of NQF #0678; therefore, we are proposing to adopt the NQF #0678 as specified (for example, including risk-adjustment) for the FY 2017 payment determination and subsequent fiscal year payment determinations.

TABLE 8—QUALITY MEASURES FINALIZED IN THE CY 2013 OPPS/ASC FINAL RULE AFFECTING THE FY 2015 IRF ANNUAL INCREASE FACTOR AND SUBSEQUENT YEAR INCREASE FACTORS

NQF Measure ID	Measure title
NQF #0138	National Health Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure +
Application of NQF #0678	Percent of Residents or Patients with Pressure Ulcers That are New or Worsened (Short-Stay) *

+ Using CDC/NHSN.
* Using October 1, 2012 release of IRF–PAI.

C. Proposed New IRF QRP Quality Measures Affecting the FY 2016 and FY 2017 IRF PPS Annual Increase Factor, and Subsequent Year Increase Factors

1. General Considerations Used For Selection of Quality Measures for the IRF QRP

The successful development of an IRF quality reporting program that promotes the delivery of high quality healthcare services in IRFs is our paramount concern. We seek to adopt measures for the IRF QRP that promote better, safer, and more efficient care. Our measure selection activities for the IRF QRP 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 1st 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 proposed rule. Input from the MAP is located at *http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*. For more details about the pre-rulemaking process, see the FY 2013 IPPS/LTCH PPS final rule (77 FR 53376).

We also take into account national priorities, such as those established by the National Priorities Partnership (NPP) at *http://www.qualityforum.org/npp/*, the HHS Strategic Plan *http://www.hhs.gov/secretary/about/priorities/priorities.html* and the National Strategy for Quality Improvement in Healthcare located at (*http://www.healthcare.gov/news/reports/nationalqualitystrategy032011.pdf*).

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 2016 IRF PPS annual increase factor, in addition to retaining the previously discussed CAUTI and Pressure Ulcer measures, we are proposing to adopt one new measure: Influenza Vaccination Coverage among Healthcare Personnel Measure (NQF #0431). For the FY 2017 IRF PPS annual increase factor we are proposing to adopt three 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). We discuss each in turn below.

2. New Quality Measures Proposed for Quality Data Reporting Affecting the FY 2016 IRF PPS Annual Increase Factor

i. Proposed IRF QRP Measure #1: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)

We propose to adopt the CDC developed Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure that is currently collected by the CDC via the NHSN. This measure reports on the percentage of health care personnel who receive the influenza vaccination. This measure was included on the CMS' List of Measures under Consideration for December 1, 2012 that CMS made publicly available. The measure was reviewed by the MAP and was included in the MAP input that was transmitted to CMS on February 1, 2013, as required by section 1890A(a)(3) of the Act. The MAP fully supported the use of this measure in the IRF setting, indicating it promotes alignment across quality reporting programs (for example, with Long-Term Care Hospital Quality Reporting Program (LTCHQR Program) and Hospital Inpatient Quality Reporting Program (Hospital IQR)) and addresses a core measure concept.

Health care personnel are at risk for both acquiring influenza from patients and transmitting it to patients, and health care personnel often come to work when ill.[2] One early report of health care personnel influenza infections during the 2009 H1N1 influenza pandemic estimated 50 percent of infected health care personnel had contracted the influenza virus from patients or coworkers in the healthcare setting.[3]

The CDC Advisory Committee on Immunization Practices (ACIP) guidelines recommend that all health care personnel get an influenza vaccine every year to protect themselves and patients.[4] Even though levels of influenza vaccination among health care personnel have slowly increased over the past 10 years, less than 50 percent of health care personnel each year received the influenza vaccination until the 2009 and 2010 seasons, when an estimated 62 percent of health care personnel got a seasonal influenza vaccination. In the 2010 and 2011 season, 63.5 percent of health care personnel reported influenza vaccination. Increased influenza vaccination coverage among health care personnel is expected to result in reduced morbidity and mortality related to influenza virus infection among patients, aligning with the NQS's aims of better care and healthy people/communities. This measure has been finalized for reporting in the Hospital IQR Program, LTCHQR Program, and the Ambulatory Surgical Center Quality Reporting Program (ASCQR Program).

We refer readers to the NHSN Manual, Healthcare Personnel Safety Component Protocol Module, Influenza Vaccination and Exposure Management Modules, which is available at the CDC Web site at *http://www.cdc.gov/nhsn/inpatient-rehab/hcp-vacc/index.html* for measure specifications and additional details.

We propose that, for the IRF QRP, the Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431) have its own reporting period to align with the influenza vaccination season, which is defined by the CDC as October 1st (or when the vaccine becomes available) through March 31st. IRFs will submit their data for this measure to the NHSN (*http://www.cdc.gov/nhsn/*). It is a secure Internet based surveillance system maintained by the CDC, and can be utilized by all types of health care facilities in the United States, including IRFs. 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 the provided web link: *http://www.cdc.gov/nhsn/*. NHSN will submit data to CMS on behalf of the facility.

For the FY 2016 IRF PPS annual increase factor, we propose that the 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 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 data, the 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 season for NQF #0431, data submission is only required once per influenza season, unlike the other measure finalized for the IRF QRP that utilizes NHSN (CAUTI measure NQF #0138). For example, IRFs can choose to submit influenza vaccination data on a monthly basis. However, each time an IRF submits these data, it will be asked to provide a cumulative total of vaccinations for the ''current'' influenza season. Thus, entering this information at the end of the influenza season would yield the same total number of vaccinations. The NHSN system will not track the individual number of vaccinations on a monthly basis, but, rather, will track the cumulative total of vaccinations for the ''current'' influenza season. We propose that the final deadline associated with this measure align with another CMS deadline for IRF HAI reporting into NHSN, which is May 15th. IRF QRP data collection timelines and submission deadlines are discussed below.

Also, we note that data collection for this measure is not 12 months, as with other measures, but is approximately 6 months (October 1 (or when the vaccine becomes available) through March 31 of the following year). We note that this data collection period is applicable only to NQF #0431 Influenza Vaccination Coverage Among Healthcare Personnel, and not applicable to any other IRF QRP

[2] Wilde JA, McMillan JA, Serwint J, *et al.* Effectiveness of influenza vaccine in healthcare professionals: A randomized trial. JAMA. 1999; 281: 908–913.

[3] Harriman K, Rosenberg J, Robinson S, *et al.* Novel influenza A (H1N1) virus infections among health-care personnel—United States, April–May 2009. MMWR Morb Mortal Wkly Rep. 2009; 58(23): 641–645.

[4] Fiore AE, Uyeki TM, Broder K, *et al.* Prevention and control of influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010. MMWR Recomm Rep. 2010. 59(08): 1–62.

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*.

We are seeking comments on the proposed use of the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure for the FY 2016 IRF PPS annual increase factor and subsequent years.

TABLE 9—SUMMARY OF FY 2016 IRF PPS ANNUAL INCREASE FACTOR

Continued Data Collection:
• NQF #0138: National Health Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure +
• Application of NQF #0678: Percent of Residents with Pressure Ulcers That are New or Worsened (Short-Stay) *
Proposed New IRF QRP Measures Affecting the FY 2016 IRF PPS Annual Increase Factor and Subsequent Year Increase Factors:
• NQF #0431: Influenza Vaccination Coverage among Healthcare Personnel +

+ Using CDC NHSN.
* Using October 1, 2012 release of IRF–PAI.

3. Quality Measures Proposed for Quality Data Reporting Affecting the FY 2017 IRF PPS Annual Increase Factor and Subsequent Years

We are proposing to adopt two additional quality measures, and replace an existing quality measure for the IRF QRP for the FY 2017 payment determination and subsequent payment determinations. The new measures being proposed are (1) All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities, and (2) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680). In addition, we propose to replace the application of Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (short-stay) (NQF #0678), with adoption of the NQF endorsed version of this measure. We discuss each in turn below.

i. Proposed IRF QRP Measure #1: All-Cause Unplanned Readmission Measure for 30 Days Post Discharge From Inpatient Rehabilitation Facilities

We propose to adopt the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities. This 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. This is a claims-based measure not requiring reporting of new data by IRFs, and hence, will not be used to determine IRF reporting compliance for the IRF QRP.

Addressing unplanned hospital readmissions is a high priority for HHS and CMS as our focus continues on promoting patient safety, eliminating healthcare associated infections, improving care transitions, and reducing the cost of healthcare. Readmissions are costly to the Medicare program and have been cited as sensitive to improvements in coordination of care and discharge planning for patients.[5] Although the literature on readmissions is mainly concerned with discharges from short-term acute hospitals, the same issues of discharge planning, communications and coordination arise at discharge from other inpatient facilities.

IRFs provide intensive rehabilitation services to patients after an injury, illness, or surgery. According to MedPAC, the average length of stay for most patients in an IRF is 13.1 days.[6] In 2010, almost 360,000 Medicare fee-for-service (FFS) beneficiaries received care in IRFs and cost the Medicare FFS program over $6 billion dollars. The unadjusted readmission rate to an IPPS hospital in the 30 days following an IRF discharge was about 15 percent.[7] With such a large proportion of patients being readmitted to a hospital level of care, we are proposing a risk-adjusted measure of readmission rate, the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities. An IRF's readmission rate is affected by complex and critical aspects of care such as communication between providers or between providers and patients; prevention of, and response to, complications; patient safety; and coordinated transitions to the community or a less intense level of care. While disease-specific measures of readmission are useful in identifying deficiencies in care for specific groups of patients, they account for only a small minority of total readmissions. By contrast, a facility-wide, all-cause readmission reflects a broader assessment of the quality of care in IRFs, and may consequently better promote quality improvement and inform consumers about quality.

While some readmissions are unavoidable, such as those resulting from the inevitable progression of disease or worsening of chronic conditions, readmissions may also result from poor quality of care or inadequate transitions between care settings. Randomized controlled trials in short-stay acute care hospitals have shown that improvement in the following areas can directly reduce hospital readmission rates: quality of care during the initial admission; improvement in communication with patients, their caregivers and their clinicians; patient education; pre-discharge assessment; and coordination of care after discharge. Successful randomized trials have reduced 30-day readmission rates by 20–40 percent.[8 9 10 11 12 13 14] and a 2011 meta-analysis of randomized clinical trials found evidence that interventions associated with discharge planning helped to reduce readmission rates,[15]

[5] **Federal Register**/Vol. 76, No. 160/Thursday, August 18, 2011/Rules and Regulations, C1a.

[6] MedPAC, Report to Congress, Medicare Payment Policy, March, 2012. *http://www.medpac.gov/chapters/Mar12_Ch09.pdf.*

[7] Bernard SL, Dalton K, Lenfestey NF, 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.

[8] Jack BW, Chetty VK, Anthony D, Greenwald JL, Sanchez GM, Johnson AE, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. Ann Intern Med 2009;150(3):178–87.

[9] Coleman EA, Smith JD, Frank JC, Min SJ, Parry C, Kramer AM. Preparing patients and caregivers to participate in care delivered across settings: the Care Transitions Intervention. J Am Geriatr Soc 2004;52(11):1817–25.

[10] Courtney M, Edwards H, Chang A, Parker A, Finlayson K, Hamilton K. Fewer emergency readmissions and better quality of life for older adults at risk of hospital readmission: a randomized controlled trial to determine the effectiveness of a 24-week exercise and telephone follow-up program. J Am Geriatr Soc 2009;57(3):395–402.

[11] Garasen H, Windspoll R, Johnsen R. Intermediate care at a community hospital as an alternative to prolonged general hospital care for elderly patients: a randomized controlled trial. BMC Public Health 2007;7:68.

[12] Koehler BE, Richter KM, Youngblood L, Cohen BA, Prengler ID, Cheng D, et al. Reduction of 30-day post discharge hospital readmission or emergency department (ED) visit rates in high-risk elderly medical patients through delivery of a targeted care bundle. J Hosp Med 2009;4(4):211–218.

[13] Naylor M, Brooten D, Jones R, Lavizzo-Mourey R, Mezey M, Pauly M. Comprehensive discharge planning for the hospitalized elderly. A randomized clinical trial. Ann Intern Med 1994;120(12):999–1006.

[14] Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, et al. Comprehensive discharge planning and home follow-up of hospitalized elders: a randomized clinical trial. Jama 1999;281(7):613–20.

[15] Naylor MD, Aiken LH, Kurtzman ET, Olds DM, Hirschman KB.The Importance of Transitional Care

illustrating how hospitals may influence readmission rates through best practices.

Because many studies have shown readmissions to be related to quality of care, and that interventions have been able to reduce 30-day readmission rates, we believe it is appropriate to include an all-condition readmission rate as a quality measure in the IRF QRP. Promoting quality improvements leading to successful transitions of care for patients moving from the IRF setting to the community or another post-acute care setting, and reducing preventable facility-wide readmission rates, is consistent with the National Quality Strategy priorities of safer, better coordinated care and lower costs.

CMS's approach to developing this measure is consistent with NQF-endorsed Hospital-Wide (HWR) Risk-Adjusted All-Cause Unplanned Readmission Measure (NQF #1789) (*http://www.qualityforum.org/Publications/2012/07/Patient_Outcomes_All-Cause_Readmissions_Expedited_Review_2011.aspx*) finalized for the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS Final Rule (FR 77 53521 through 53528). To the extent appropriate, the proposed IRF measure is being harmonized with the HWR measure and other measures of readmission rates developed for post-acute care (PAC) settings, including LTCHs.

The All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities measure assesses returns to short-stay acute care hospitals or LTCHs within 30 days of discharge from an IRF to the community or another care setting of lesser intensity. Patient readmissions are tracked using Medicare claims data for 30 days after discharge, to the date of patient death, if the patient dies within 30 days of discharge. Because patients differ in complexity and morbidity, the measure is risk-adjusted for patient case-mix. The measure also excludes planned readmissions, because these are not considered to be indicative of poor quality of care on the part of the IRF.

A model developed by a CMS measure development contractor predicts admission rates while accounting for patient demographics, primary condition in the prior short stay, comorbidities, and a few other patient factors. While estimating the predictive power of the patient characteristics, the model also estimates a facility specific effect common to patients treated at that facility. Similar to the Hospital IQR Program hospital-wide readmission measure, the proposed IRF QRP measure is the ratio of the number of risk-adjusted predicted unplanned readmissions for each individual IRF, including the estimated facility effect, to the average number of risk-adjusted predicted unplanned readmissions for the same patients treated across IRFs. A ratio above one indicates a higher than expected readmission rate, or lower level of quality, while a ratio below one indicates a lower than expected readmission rate, or higher level of quality (The methodology report detailing the development of the IPPS hospital-wide measure and the NQF report may be downloaded from: *http://www.qualityforum.org/Publications/2012/07/Patient_Outcomes_All-Cause_Readmissions_Expedited_Review_2011.aspx*.)

The patient population includes IRF patients who:

- Were discharged alive from the IRF
- Had 12 months of Medicare Part A, fee-for-service coverage prior to the IRF stay
- Had 30 days of Medicare Part A, fee-for-service coverage post discharge.
- Had an IPPS hospital stay within the 30 days prior to the IRF stay.
- Were aged 18 years or above when admitted to the IRF.

As with the Hospital IQR Program hospital-wide readmission measure, patients whose principal diagnosis was cancer and whose treatment was non-surgical are excluded. Studies of this population that were reviewed for the Hospital IQR Program readmission measure showed them to have a different trajectory of illness and mortality than other patient populations.[16] The measure also excludes patients who died during the IRF stay, IRF patients under the age of 18, or IRF patients discharged against medical advice (AMA).

Readmissions that are not included in the measure are:

- Transfers from an IRF to another IRF or IPPS hospital
- Readmissions within the 30 day window that are usually considered planned due to the nature of the procedures and principal diagnoses of the readmission.
- IRF stays that are problematic (e.g., with stays that overlap wholly or in part)

The planned readmission list includes the planned procedures specified in the Hospital-Wide All-Cause Unplanned Readmission Measure (HWR) (NQF #1789) used in the Hospital IQR Program, plus other procedures that were determined in consultation with technical expert panels. In addition to the list of planned procedures is a list of diagnoses which, if found as the principal diagnosis on the readmission claim, would indicate that the procedure occurred during an unplanned readmission.

A discharged patient is tracked until one of the following occurs: (1) The 30-day period ends; (2) the patient dies; or (3) the patient is readmitted to an acute level of care (short or long term). If multiple readmissions occur, only the first is considered for this measure. If the readmission is unplanned, it is counted as a readmission in the measure rate. If the readmission is planned, the readmission is not counted in the measure rate. The occurrence of a planned readmission ends the 30-day window of the index discharge from the IRF.

Readmission rates are risk-adjusted for patient case-mix characteristics, independent of quality. The risk-adjustment model accounts for demographic characteristics, principal diagnosis, co-morbidities, length of stay in the prior IPPS hospital, critical care days in the prior IPPS hospital, number of IPPS hospital stays in the prior year, and the occurrence of various surgery types in the prior IPPS hospital stay. In modeling IRF readmissions, all patients are included in a single model modeling separate patient types separately as was done in the IPPS measure, an approach different from the five-cohort approach of the HWR measure, adapted to account for a substantially smaller patient population.

While the HWR measure used one year of data, the smaller IRF patient population leads us to propose merging two years of data for the IRF QRP. This approach is similar to that used by the Hospital IQR Program condition-specific readmission measures, which use three years of claims data. Merging multiple years produces more precise estimates of the effects of all the risk adjusters, and increases the sample size associated with each facility. Larger patient samples are better to be able to meaningfully to distinguish facility performance. Under the exception authority in section 1886(m)(5)(D)(ii) of the Act, we are proposing to use this measure in the IRF QRP. 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

in Achieving Health Reform. Health Affairs 2011; 30(4):746–754.

[16] National Quality Forum. ''Patient Outcomes: All-Cause Readmissions Expedited Review 2011''. July 2012. pp12

contract under section 1890(a), 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.

We were not able to identify an appropriate readmission measure for IRFs. In 2012, NQF endorsed two hospital-wide readmission measures, the National Committee for Quality Assurance (NCQA) measure intended for health plans, Plan All-Cause Readmissions (NQF #1768), and CMS' Hospital-Wide All-Cause Unplanned Readmission Measure (HWR) (NQF #1789), of which the latter is the basis of the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities measure being proposed here. This measure was present on CMS's List of Measures Under Consideration, and the most recent MAP Pre-Rulemaking Report noted that ''readmission measures are also examples of measures that MAP recommends be standardized across settings, yet customized to address the unique needs of the heterogeneous Post-Acute Care/Long-Term Care (PAC/LTC) population. (*http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-February_2013.aspx pp. 177-180*). Although supported the direction of this measure, they cautioned that required further development. MAP has also continually noted the need for care transition measures in PAC/LTC performance measurement programs. Setting-specific admission and readmission measures under consideration would address this need''.[17]

We intend to seek NQF endorsement of the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities measure. As this is a claims-based measure not requiring reporting of new data by IRFs, this measure will not be used to determine IRF reporting compliance for the IRF QRP. We are proposing to begin reporting feedback to IRFs on performance of this measure in CY 2016. The initial provider feedback will be based on CY 2013 and CY 2014 Medicare FFS claims data related to IRF readmissions. The readmission measure will be part of the IRF public reporting program once public reporting is instated. Additional Details pertaining to this measure can be found on the IRF Quality Reporting Program Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html*. We intend to provide details pertaining to the public reporting, such as provider preview of performance results, of this measure in our upcoming rules.

We seek public comment on our proposal to adopt the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities.

ii. Proposed IRF QRP Quality Measure #2: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)

We are proposing to add the NQF# 0680 Percent of Residents or Patients who were assessed and Appropriately Given the Seasonal Influenza Vaccination (Short-Stay) measure to the IRF QRP, and we propose to collect the data for this measure through the addition of data items to the Quality Indicator section of the IRF–PAI. This measure was on CMS's list of measures under consideration that were reviewed by the MAP and was included in the MAP input that was transmitted to CMS, as required by the pre-rulemaking process in section 1890A(a)(3) of the Act. The MAP panel supported the use of this measure in the IRF setting, noting that it promotes alignment across settings and addresses a core measure concept. A MAP finding of ''supported'' indicates the measure is appropriate for immediate inclusion in the program measure set. (MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS, Pages 20 and 178, February 2013).

Although influenza is prevalent among all population groups, the rates of death and serious complications related to influenza are highest among those ages 65 and older and those with medical complications that put them at higher risk. The CDC reports that an average of 36,000 Americans die annually from influenza and its complications, and most of these deaths are among people 65 years of age and over.[18] In 2004, approximately 70,000 deaths were caused by influenza and pneumonia, and more than 85 percent of these deaths were among the elderly.[19] Given that many individuals receiving health care services in IRFs are elderly and/or have several medical conditions, many IRF patients are within the target population for the influenza immunization.[20] [21]

We propose to add the data elements needed for this measure, as an influenza data item set, to the Quality Indicator section of the IRF–PAI. This item set is described below entitled, ''*Proposed Changes to the IRF–PAI That Are Related to the IRF Quality Reporting Program.*'' We are proposing that data for this measure will be collected using a revised version of the IRF–PAI that includes a new data item set designed to assess patients' influenza vaccination status. The revised IRF–PAI would be effective on October 1, 2014. These proposed data set items are harmonized with data elements (O0250: Influenza Vaccination Status) from the Minimum Data Set (MDS) 3.0 and LTCH CARE Data Set item sets.[22] [23] The specifications and data elements for this proposed measure are available in the MDS 3.0 QM User's Manual available on our Web site at *https://www.cms.gov/NursingHomeQualityInits/Downloads/MDS30QM-Manual.pdf*.

For purposes of this measure, the influenza vaccination season consists of October 1st (or when the vaccine becomes available) through March 31st each year. We are proposing that while an IRF's compliance with reporting quality data for this measure will be based on the calendar year, the measure calculation and public reporting of this

[17] National Quality Forum. *Measure Applications Partnership Pre-Rulemaking Report: 2013 Recommendations of Measures Under Consideration by HHS: February 2013.* Available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72738.*

[18] Centers for Medicare & Medicaid Services (2011, May). Adult Immunization: Overview. Retrieved from *https://www.cms.gov/Immunizations/.*

[19] Gorina Y, Kelly T, Lubitz J, *et al.* (2008, February). Trends in influenza and pneumonia among older persons in the United States. Aging Trends no. 8. Retrieved from *http://www.cdc.gov/nchs/data/ahcd/agingtrends/08influenza.pdf.*

[20] Centers for Disease Control and Prevention. (2008, September). Influenza e-brief: 2008–2009 flu facts for policymakers. Retrieved from *http://www.cdc.gov/washington/pdf/flu_newsletter.pdf.*

[21] Zorowitz, RD. Stroke Rehabilitation Quality Indicators: Raising the Bar in the Inpatient Rehabilitation Facility. Topics in Stroke Rehabilitation 2010; 17 (4):294–304.

[22] Centers for Medicare & Medicaid Services. MDS 3.0 Item Subsets VI.10.4 for the April 1, 2012 Release. Retrieved from *https://www.cms.gov/NursingHomeQualityInits/30_NHOIMDS30TechnicalInformation.asp.*

[23] The LTCH CARE Data Set Version 2.00, the data collection instrument for the submission of the Percent of Residents or Patients with Pressure Ulcers That are New or Worsened (Short-Stay) measure and the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) measure, is currently under review by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act (PRA) *http://www.gpo.gov/fdsys/pkg/FR-2013-02-01/pdf/2013-02155.pdf.* The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938–1163. Expiration Date April 30, 2013.

measure (once public reporting is instated) will be based on the influenza vaccination season starting on October 1 (or when vaccine becomes available) and ending on March 31 of the subsequent year.

The IRF–PAI Training Manual will indicate how providers should complete these items during the time period outside of the vaccination season (October 1 (or when vaccine becomes available) through March 31). 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: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIQualityMeasures.html*. Measure specifications are located in the download titled: MDS 3.0 QM User's Manual V6.0. Additional information on this measure can also be found at *http://www.qualityforum.org/QPS/0680*. Additional discussion related to the timing and submission of this measure is provided in this proposed rule.

We invite public comment on our proposal to use the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680) measure for the FY 2017 IRF PPS annual increase factor and subsequent years.

iii. Proposed IRF QRP Quality Measure #3: Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678)—Proposal To Adopt the NQF Endorsed Version of This Measure

In the CY 2013 OPPS/ASC final rule (77 FR 68507) we finalized adoption of a non-risk-adjusted application of this measure, using the IRF–PAI released on October 1, 2012 for data collection. Although the measure was expanded to the IRF setting in 2012, the existing IRF–PAI needed to be updated to include the additional data elements required to risk adjust the measure prior to adopting the NQF measure. We also stated that we would not begin public reporting of this measure until we had adopted the NQF-endorsed version of this measure, and we would use the rulemaking process to solicit public comments on changes made to the IRF–PAI to collect elements necessary for risk adjustment of NQF #0678 (77 FR 68507).

If these proposed data elements related to risk adjustment data element are finalized, we also propose to remove the use of the currently adopted non-risk adjusted application of the measure and adopt the NQF-endorsed version of NQF #0678 for the FY 2017 IRF PPS increase factor. NQF #0678 underwent review for expansion to the IRF setting by the NQF Consensus Standards Approval Committee (CSAC) on July 11, 2012 and was subsequently ratified by the NQF Board of Directors for expansion to IRF settings on August 1, 2012.[24] [25] The title of the measure was changed to Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (short-stay) to reflect this expansion. Updated specifications, reflecting the expansion, are available on the NQF Web site at *http://www.qualityforum.org/QPS/0678*. We further propose to collect data for this measure using a revised version of the IRF–PAI beginning on October 1, 2014 for the FY 2017 IRF PPS annual increase factor. Our proposals related to a revised IRF–PAI are discussed in this proposed rule. The measure specifications for this NQF endorsed measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (short-stay) (NQF #0678) can be found on the CMS Web site: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIQualityMeasures.html*. Measure specifications are located in the download titled: MDS 3.0 QM User Manual V6.0. Additional information about the measure can also be found at *http://www.qualityforum.org/QPS/0678*.

In summary, we propose to adopt the NQF-endorsed version of NQF #0678, with data collection beginning October 1, 2014 using the revised version of IRF–PAI, for quality reporting affecting the FY 2017 IRF PPS annual increase factor. Further, we propose to remove the current non-risk adjusted application of this measure when the revised IRF–PAI is implemented on October 1, 2014. Note that until September 30, 2014, IRFs should continue to submit pressure ulcer data using the IRF–PAI released on October 1, 2012 for the purposes of data submission requirements for the FY 2015 and FY 2016 IRF PPS increase factor. Changes to the IRF–PAI and additional information regarding data submission are discussed in this proposed rule.

We invite public comment regarding our proposed removal of the currently adopted non-risk adjusted application of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (short-stay) (NQF #0678) and the adoption of the NQF endorsed version of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678).

TABLE 10—SUMMARY OF FY 2017 IRF PPS ANNUAL INCREASE FACTOR

Continued Data Collection:
- NQF #0138: National Health Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure +

Continued Data Collection of Proposed New IRF QRP Measures Affecting the FY 2016 IRF PPS Annual Increase Factor:
- NQF #0431: Influenza Vaccination Coverage among Healthcare Personnel +

Proposed New IRF QRP Measures Affecting the FY 2017 IRF PPS Annual Increase Factor:
- 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) *

+ Using CDC/NHSN.
* Using the IRF–PAI released October 1, 2014.
caret; Medicare Fee-For-Service claims data.

[24] National Quality Forum, Consensus Standards Approval Committee Wednesday, July 11, 2012. Transcript. Available: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=71612*.

[25] Press Release: NQF Removes Time-Limited Endorsement Status for 13 Measures, Measures Now Have Endorsed Status. August 1, 2012. Available: *http://www.qualityforum.org/News_And_Resources/Press_Releases/2012/NQF_Removes_Time-Limited_Endorsement_for_13_Measures;_Measures_Now_Have_Endorsed_Status.aspx*.

D. Proposed Changes to the IRF–PAI That Are Related to the IRF Quality Reporting Program

1. General Background

A version of the IRF–PAI has been in use in the IRF setting since January 1, 2002, when IRFs first began receiving payment under the IRF PPS. IRFs must submit a completed IRF–PAI for each Medicare Part A, B, and C patient that is admitted and discharged from the IRF.

The IRF PPS utilizes information from the IRF–PAI to classify patients into distinct groups based on clinical characteristics and expected resource needs. Separate payments are calculated for each group, including the application of case and facility level adjustments available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/index.html*.

We are proposing to release an updated version of the IRF–PAI on October 1, 2014. Proposed revisions include data elements that will (1) Allow for risk adjustment of the NQF #0678 Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay), (2) allow for more detailed data collection related to NQF #0678 Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay), and (3) allow for data collection for NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay). We also propose to adopt a new numbering schema for the IRF–PAI.

Note that we are proposing both mandatory and voluntary additions to the IRF–PAI. Collection of voluntary data elements by IRFs will have no impact on measure calculations or on our determination of whether the IRF has met the reporting requirements under the IRF QRP. In contrast, failure to complete any adopted mandatory data elements may result in non-compliance with the IRF QRP requirements and subject the facility to a 2 percentage point reduction in its annual increase factor. In addition to clearly indicating which items are mandatory and which are voluntary in this proposal, we will post on our Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html* a detailed matrix that identifies which data elements will be required, and which will be voluntary.

The October 1, 2012 release of the IRF–PAI, the proposed October 1, 2014 release of the IRF–PAI, inclusive of all the changes proposed here, and information about the IRF–PAI submission process can be found at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html*. A PRA package for the revised IRF–PAI discussed here has been submitted for the Office of Management and Budget's (OMB) review and approval.

2. Background Related To Collection of Pressure Ulcer Data Elements Using the IRF–PAI

In the FY 2012 IRF PPS final rule, we finalized a proposal to adopt an application of the NQF #0678 ''Percent of Residents with Pressure Ulcers That Are New or Worsened (Short-Stay)'' measure for use in the IRF QRP, beginning with the IRF PPS annual increase factor for FY 2014. We also finalized our proposal to collect the data for this pressure ulcer measure using the IRF–PAI. To do this, we deleted the set of voluntary quality questions that had been located in the ''Quality Indicator'' section of the IRF–PAI and replaced them with a new required set of pressure ulcer quality measure data items, numbered 48A to 50D. These revisions to the IRF–PAI went into effect on October 1, 2012.

Since the publication of the FY 2012 IRF PPS final rule we have received numerous comments about the current version of the IRF–PAI from IRF providers, provider organizations, and advocacy groups. In the CY 2013 OPPS/ASC final rule, we discussed a number of specific public comments related to pressure ulcer data that we received in response to the CY 2013 OPPS/ASC IRF proposed rule (77 FR 68506). Commenters expressed specific concerns regarding the ability of the data elements in the IRF–PAI to sufficiently risk-adjust the measure. We agreed that there were limitations related to the risk adjustment data items that are on the IRF–PAI that went into effect on October 1, 2012, impacting the ability to calculate the measure using all of the risk adjustment related covariates. As a result, the CY 2013 OPPS/ASC final rule adopted an application of #0680 without risk-adjustment for FY 2015 and subsequent years (77 FR 68507).

In response to the comments and feedback received in previous rules discussed above, we propose modifications to the data items in both the admission and discharge IRF–PAI assessments.

3. Proposed Revisions to the IRF–PAI To Add Mandatory Risk Adjustment Data Items for NQF #0678 Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short-Stay)

We are proposing to update the current IRF–PAI to include data elements that are necessary to risk adjust the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay) (NQF #0678). These include the addition of the following indicator boxes to the IRF–PAI admission assessment: (1) Peripheral Vascular Disease, (2) Peripheral Arterial Disease, and (3) Diabetes. The additions would be placed in the Quality Indicators section of the revised IRF–PAI.

We further determined that risk adjustment factors related to height and weight had inadvertently been left off of the revised version of the IRF–PAI that became effective on October 1, 2012. We are now proposing to add height and weight to the IRF–PAI to correct this oversight.

We further propose adding the height and weight items into the ''Medical Information'' section if the IRF–PAI. As a general rule, we would place all data items related to quality reporting and quality measures within the Quality Indicator section of the IRF–PAI. However, the height and weight items have a dual purpose because they can be used for the calculation of Body Mass Index (BMI), which is used as one part of the analysis for compliance with the 60 percent rule. Even though the height and weight items are placed in the ''Medical Information'' section of the IRF–PAI, they are also being added to the IRF–PAI for calculating risk adjustment for the pressure ulcer measure. Failure to provide height and weight could result in a finding of non-compliance with the reporting requirements.

We invite public comment on our proposal to include data elements required for risk-adjustment of #0678 Percent of Patients with Pressure Ulcers That Are New or Worsened Measure as mandatory data collection elements in the revised IRF–PAI.

4. Proposed Revisions to the IRF–PAI To Add Voluntary Data Items Related to NQF #0678 Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short-Stay)

The pressure ulcer measure numerator for the NQF #0678 endorsed version of the ''Percent of Patients with Pressure Ulcers That Are New or Worsened'' measure looks at the number

of patients with a target assessment during the selected time window who have one or more Stage 2 through 4 pressure ulcer(s) that are new or that have worsened compared with the previous assessment. According to the NQF Web site, in its description of NQF #0678, ''Stage 1 pressure ulcers are excluded from this measure because recent studies have identified difficulties in objectively measuring them across different populations.'' The measure numerator also does not include unstageable pressure ulcers. The data that is mandatory for IRFs to report under the IRF QRP are those that meet the requirements of the application of NQF #0678 that we finalized in the CY 2013 OPPS/ASC Final Rule. As noted above, we are proposing to add additional mandatory data items to accommodate this. If our proposal to adopt the NQF-endorsed version of this measure is finalized, the mandatory data would remain the same.

We are also proposing to add voluntary data items to the IRF–PAI Quality Indicators section, designed to address commenters' concerns about the adequacy of current pressure ulcer data items. Some commenters expressed concern that the current data items would not allow for documentation of all relevant categories of pressure ulcers, such as unstageable pressure ulcers. As modified, our proposed admission assessment consists of 2 main topics: (1) Unhealed Pressure Ulcers; and (2) Pressure Ulcer Risk Conditions. Also, the discharge assessment consists of 2 main topics: (1) Unhealed Pressure Ulcers; and (2) Healed Pressure Ulcers. Within each main topic there are sub-topics that contain a set of questions. The provider is asked to document how many pressure ulcers, if any, the patient has at each stage upon admission. We have added new questions that extend beyond stages 2 through 4 pressure ulcers, covering the presence of stage 1 pressure ulcers, as well as unstageable pressure ulcers that are due to a non-removable device or dressing, to slough or eschar, or deep tissue injury. We note that the discharge assessment differs somewhat from the admission assessment with regard to the pressure ulcer questions. A copy of the proposed new IRF–PAI can be found at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html*.

We have added greater specificity to the pressure ulcer items to allow providers to document pressure ulcers in more detail. In describing the inadequacy they perceived in the present pressure ulcer items, providers described such situations as those in which a patient is admitted into an IRF with an unstageable pressure ulcer that is a suspected deep tissue injury (DTI). During the course of the IRF stay the DTI evolves into a stage 3 and, after several days, worsens to a stage 4. On the current version of the IRF–PAI, providers have no ability to document the presence of an unstageable pressure ulcer that existed when the patient was admitted. Whether or not the IRF believes there is an unstageable pressure ulcer, the IRF must document that the patient had no pressure ulcers on the admission assessment. However later, after the DTI worsens to a stage 3, if the IRF judges from the nature of the pressure ulcer that it was extremely likely to have been present at admission, the IRF would have to go back and change their documentation on the admission assessment to reflect that the patient actually had a stage 3 pressure ulcer upon admission. Upon discharge, the IRF would document that the patient has a stage 4 pressure ulcer. With the new proposed pressure ulcer data items, the IRF would be able to document the presence of the unstageable pressure ulcer or suspected DTI on the admission assessment. The proposed revisions to the IRF–API would allow the IRF to give a more complete and accurate picture of the progression of this pressure ulcer when the patient is discharged.

While Stage 1 and unstageable pressure ulcers are not part of the NQF #0678 endorsed version of the ''Percent of Patients with Pressure Ulcers That Are New or Worsened,'' and are not mandatory, we nonetheless believe that it is appropriate and important for us to collect this information. As the measure steward for this measure, CMS would like to gather and analyze data regarding Stage 1 and unstageable pressure ulcers to help determine if any modification to the existing measure should be made. This data could also help us determine if any additional pressure ulcer measures should be developed. For example, collecting data about Stage 1 pressure ulcers could provide us with information that would allow us to assess whether these pressure ulcers can now be objectively measured across different populations.

Additionally, some pressure ulcers that are present on admission can become stageable and then worsen to a higher stage during the IRF stay. Access to data on this scenario would assist us in determining whether including unstageable and Stage 1 measures in the measure results may be appropriate in the future. We might accomplish this by expanding the current measure or developing an entirely new pressure ulcer measure.

We invite public comment on our proposed revisions to the IRF–PAI related to voluntary items for NQF #0678 Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay).

5. Proposed Revisions to the IRF–PAI to Add Mandatory Data Items related to NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay)

We are also proposing changes to the IRF–PAI discharge assessment to include the addition of the data elements necessary to report the data necessary for the proposed measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680). These items will be based on the items from the MDS 3.0 and LTCH CARE Data Set items.[26] [27] There are three data elements collected in relation to this measure: Two are used to calculate the measure and a third is used to ensure internal consistency and data accuracy. The items are as follows: Did the patient receive the influenza vaccine in this facility for this year's influenza vaccination season? Date influenza vaccine was received; and, If influenza vaccine not received, state reason. These questions allow the IRF to report if and when an influenza vaccine was given at the facility. It also allows the IRF to indicate why a vaccine was not given if that is the case. Further details on the specifications and data elements for this measure are available in the MDS 3.0 QM User's Manual available on our Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIQualityMeasures.html*. Measure specifications are located in the download titled: MDS 3.0 QM User's

[26] Centers for Medicare & Medicaid Services. MDS 3.0 Item Subsets V1.10.4 for the April 1, 2012 Release. Retrieved from *https://www.cms.gov/NursingHomeQualityInits/30_NHQIMDS30TechnicalInformation.asp*.

[27] The LTCH CARE Data Set Version 2.00, the data collection instrument for the submission of the Percent of Residents or Patients with Pressure Ulcers That are New or Worsened (Short-Stay) measure and the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) measure, is currently under review by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act (PRA) *http://www.gpo.gov/fdsys/pkg/FR-2013-02-01/pdf/2013-02155.pdf*. The LTCH CARE Data Set Version 1.01 was approved on April 24, 2012 by OMB in accordance with the PRA. The OMB Control Number is 0938–1163. Expiration Date April 30, 2013.

Manual V6.0. Measure information is also available at *http://www.qualityforum.org/QPS/0680*.

We invite public comment on our proposed revisions to the IRF–PAI related to NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay).

6. Proposed Revisions to the IRF–PAI Related to Numbering of Quality Indicator Items.

Finally, in the revised IRF–PAI, we include changes in the numbering scheme used in the Quality Indicator section of the IRF–PAI from a ''consecutive numbering scheme'' for numbering assessment items to a numbering scheme that allows greater flexibility for item removal and insertion. Problems arise with a consecutive numbering scheme when items are removed or new ones are inserted because this changes the numbers of some or all of the items around them. Other CMS post-acute care data collection vehicles, such as the MDS 3.0, and the LTCH CARE Data Set, have adopted a more flexible numbering schema that allows insertion or removal of items without requiring renumbering of the remaining items. We propose adopting a similar numbering schema in the revised IRF–PAI. A less flexible numbering system that necessitates renumbering items on the IRF–PAI in the event of such changes will result in a given item number having very different meanings on different versions of the IRF–PAI item set.

For more details about our plans for changes to the IRF–PAI, see *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRFPAI.html*.

We invite public comments about our proposed changes to the numbering schema of the IRF–PAI.

E. Proposed Change in Data Collection and Submission Periods for Future Program Years

The FY 2012 IRF PPS final rule included an initial framework for the IRF QRP. In that rule we also finalized the initial quality measures to be used in the IRF QRP, stated how data for these measures would to be collected, and selected the time periods for the data collection and reporting of the quality data.

The FY 2012 IRF PPS final rule finalized the initial IRF QRP data reporting cycle, affecting the FY 2014 payment determination, as beginning on October 1, 2012 and ending on December 31, 2012. Beginning in 2013 for the FY 2015 payment determination, and for subsequent years, we finalized that quality reporting cycles be based on a full calendar year (CY) cycle (76 FR 47879).

When there are new measures added to the quality reporting program that will be collected on the IRF–PAI, that data collection instrument must be updated accordingly. The next update to the IRF–PAI will take place on October 1, 2014. Under current policy, the IRF QRP data collection cycle for the FY 2016 payment determination will not begin until January 1, 2014.

To accommodate the revised data collection instrument, we are proposing to change the IRF–PAI data collection periods for the FY 2016 and FY 2017 payment determinations in order to align with the release of the new version of the IRF–PAI on October 1, 2014. We propose to shorten the data collection period impacting the FY 2016 IRF PPS annual increase factor to nine months, so that the next reporting period may begin on October 1, 2014 using the new version of the IRF–PAI. Under this proposal, the next data collection period would run from January 1, 2014 to September 30, 2014 and affect the IRF PPS annual increase factor for FY 2016.

Starting October 1, 2014, we propose to start fiscal year data collection periods, such that data collected for discharges during October 1, 2014 to September 30, 2015 will affect the FY 2017 IRF PPS annual increase factor. We further propose that data collection continue on FY cycles unless there is an event that requires that this cycle be amended. We intend to provide public announcements in the event the established cycles must be changed.

Note that, as a result of this proposal, data submitted on the IRF–PAI and data submitted using the NHSN will have two separate data collection and submission schedules. We provide more details on this distinction below. We invite public comment on our proposal to alter the IRF–PAI data collection periods impacting the FY 2016 and FY 2017 increase factors in a way that aligns with the release of the next version of the IRF–PAI instrument.

1. Proposed Implementation of Quarterly Data Submission Deadlines for the IRF QRP

In the FY 2012 IRF PPS rule we stated that ''details regarding data submission and reporting requirements for this measure will be posted on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html* no later than January 31, 2012'' (FR 76 47879). Further data submission details for the IRF QRP were posted on the CMS IRF QRP Web site on January 31, 2012, as promised. In addition, data submission details were disseminated to IRFs at various times from January 31, 2012 to December 31, 2012, through an in-person training held on May 2, 2012, Open Door Forums, list-serve announcements, IRF QRP Web page postings and responses to IRF QRP Helpdesk inquiries. In these communications, we announced that the final data submission deadline for the IRF QRP would be May 15th for all measures finalized for the FY 2014 payment determination and each subsequent payment determination.

We realize the value in providing clear submission deadlines for the IRF QRP and we believe that we should provide deadlines that clearly distinguish between data submitted using the NHSN and data submitted using the IRF–PAI. Further, it is important to have distinct deadlines at which point data submitted afterward, including data modifications and corrections, could not be used for reporting or IRF PPS annual increase factor determinations. For purposes of the FY 2016 and subsequent year IRF PPS annual increase factors, and for the purposes of applying quarterly deadlines for public reporting purposes, we propose the inclusion of quarterly data submission deadlines in addition to the previously finalized deadlines. We believe that this will ensure timely submission of data.

2. Quarterly Submission Timelines of Data Reported Using the IRF–PAI

For the purposes of quality data reported using the IRF–PAI for the IRF QRP, we have proposed timeframes described below that we believe will provide sufficient time for IRFs and CMS to meet quality reporting requirements and allow CMS to harmonize IRF QRP data submission deadlines with the LTCHQR Program and Hospital IQR. Beginning with data collection and reporting impacting the FY 2016 annual increase factor, we propose that IRFs follow the deadlines presented in the tables below to complete submission of data for each quarter. For each quarter outlined in the tables below during which IRFs are required to collect data, we propose a final deadline occurring approximately 135 days after the end of each quarter by which all data collected during that quarter must be submitted. We believe that this is a reasonable amount of time to allow IRFs to submit data and make any necessary corrections. We have summarized these deadlines in the tables below.

TABLE 11—PROPOSED TIMELINES FOR SUBMISSION OF IRF QRP PROGRAM QUALITY DATA USING IRF–PAI * FOR FY 2016 IRF PPS ANNUAL INCREASE FACTOR +: APPLICATION OF NQF #0678 PERCENT OF RESIDENTS OR PATIENTS WITH PRESSURE ULCERS THAT ARE NEW OR WORSENED (SHORT-STAY)

Quarter	IRF–PAI data collection period	IRF–PAI data submission deadline for corrections of the IRF QRP
FY 2016 Annual Increase Factor		
Quarter 1	January 1, 2014–March 31, 2014	August 15, 2014.
Quarter 2	April 1, 2014–June 30, 2014	November 15, 2014.
Quarter 3	July 1, 2014–September 30, 2014	February 15, 2015.

* Using October 1, 2012 release of IRF–PAI.
+ FY 2016 APU determination is based on 3 quarters of data submission for the pressure ulcer measure.

TABLE 12—PROPOSED TIMELINES FOR SUBMISSION OF IRF QRP PROGRAM QUALITY DATA USING IRF–PAI * FOR FY 2017 IRF PPS ANNUAL INCREASE FACTOR: NQF #0678 PERCENT OF RESIDENTS OR PATIENTS WITH PRESSURE ULCERS THAT ARE NEW OR WORSENED (SHORT-STAY), AND NQF #0680 PERCENT OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE (SHORT-STAY)

Quarter	IRF–PAI data collection period	IRF–PAI data submission deadline for corrections of the IRF QRP
FY 2017 Annual Increase Factor		
Quarter 1	October 1, 2014–December 31, 2014	May 15, 2015.
Quarter 2	January 1, 2015–March 31, 2015	August 15, 2015.
Quarter 3	April 1, 2015–June 30, 2015	November 15, 2015.
Quarter 4	July 1, 2015–September 30, 2015	February 15, 2016.

* Using October 1, 2014 release of IRF–PAI.

3. Quarterly Submission Timelines of Data Reported Using NHSN

For the purposes of reporting quality data using the NHSN, specifically CAUTI reporting and reporting of the staff influenza immunization measure, we are specifically proposing to align with CMS's established submission deadlines in the Hospital IQR and the LTCHQR Programs. The CDC recommends that a facility report Healthcare Acquired Infection (HAI) events such as CAUTI, as close to the time of the event as is possible, and certainly within 30 days. CMS recommends adherence to this approach. In addition, we propose that IRFs report CAUTI events, including null events, on a monthly level using the NHSN.

For the purposes of continuity, we propose to continue the calendar year basis of reporting CAUTI, using quarterly deadlines as established by the Hospital IQR program. Final submission deadlines for measures collected through the NHSN are shown in the tables below.

TABLE 13—PROPOSED TIMELINES FOR SUBMISSION OF IRF QRP PROGRAM QUALITY DATA USING CDC/NSHN FOR FY 2016 AND FY 2017 IRF PPS ANNUAL INCREASE FACTOR: NATIONAL HEALTH SAFETY NETWORK (NHSN) CATHETER-ASSOCIATED URINARY TRACT INFECTION (CAUTI) OUTCOME MEASURE

Quarter	CDC/NHSN data collection period	CDC/NHSN data submission deadline
FY 2016 Annual Increase Factor		
Quarter 1	January 1, 2014–March 31, 2014	August 15, 2014.
Quarter 2	April 1, 2014–June 30, 2014	November 15, 2014.
Quarter 3	July 1, 2014–September 30, 2014	February 15, 2015.
Quarter 4	October 1, 2014–December 31, 2014	May 15, 2015.
FY 2017 Annual 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.

Further, we propose to apply to IRF QRP the same deadlines established for the reporting of the Influenza Vaccination Coverage Among Health Personnel (NQF #0431) measure in the Hospital IQR Program and proposed in the LTCH QRP.

TABLE 14—PROPOSED TIMELINES FOR SUBMISSION OF IRF QRP PROGRAM QUALITY DATA USING CDC/NSHN FOR FY 2016 AND FY 2017 IRF PPS ANNUAL INCREASE FACTOR: NQF #0431 INFLUENZA VACCINATION COVERAGE AMONG HEALTHCARE PERSONNEL

Data collection timeframe	CDC/NHSN Data submission deadline
FY 2016 Annual Increase Factor	
October 1, 2014 (or when the influenza vaccine becomes available)—March 31, 2015	May 15, 2015.
FY 2017 Annual Increase Factor	
October 1, 2015 (or when the influenza vaccine becomes available)—March 31, 2016	May 15, 2016.

We invite public comment on the proposed data submission quarterly and final deadlines for the purposes of reporting data using the IRFPAI and for the purposes of reporting data using the NHSN.

F. Proposed Reconsideration and Appeals Process

At the conclusion of any given data reporting period, we will review the data received from each IRF during that reporting period to determine if the IRF has reported the required amount and type of data. IRFs that are found to be non-compliant with the reporting requirements set forth for that reporting cycle could receive a reduction in the amount of 2 percentage points to their IRF PPS increase factor for the upcoming payment year.

We are aware that there may be situations in which an IRF provider has evidence to dispute a finding of non-compliance. We further understand that there may be times when a provider may be prevented from submitting quality data due to the occurrence of extraordinary circumstances beyond their control (for example, natural disasters). It is our goal not to penalize IRF providers in these circumstances or to unduly increase their burden during these times.

We are also aware, for the purposes of the IRF Quality Reporting Program, that we will be making compliance determinations for the FY 2014 payment determination in the coming months and believe that providers should have the opportunity to request a reconsideration if the circumstances warrant. In addition, adding a reconsideration process to the IRF Quality Reporting program will make it consistent with other established quality reporting programs, a number of which already offer this opportunity. We are therefore providing a mechanism that will allow IRFs to request reconsiderations pertaining to their FY 2014 payment determinations and that of subsequent fiscal years.

Specifically, as part of the mechanism to allow for IRFs to request a reconsideration, IRFs found to be non-compliant with the reporting requirements during a given reporting cycle will be notified of that finding. IRFs will be informed: (1) That they have been identified as being non-compliant with the IRF Quality Reporting Program's reporting requirements for the reporting cycle in question; (2) that they will be scheduled to receive a reduction in the amount of 2 percentage points to their PPS increase factor for the upcoming payment year; (3) that they may file a request for reconsideration if they believe that the finding of non-compliance is erroneous, or that if they were non-compliant, they have a valid and justifiable excuse for this non-compliance; and (4) that they must follow a defined process on how to file a request for reconsideration, which will be described in the notification.

Upon the conclusion of our review of each request for reconsideration, we will render a decision. We may reverse our initial finding of non-compliance if: (1) The IRF provides proof of full compliance with all requirements during the reporting period; or (2) the IRF provides adequate proof of a valid or justifiable excuse for non-compliance if the IRF was not able to comply with requirements during the reporting period. We will uphold our initial finding of non-compliance if the IRF cannot show any justification for non-compliance.

We intend to provide details pertaining to the reconsideration process, and the mechanisms related to provider requests for reconsideration of their payment determinations, such as filing requests, required content, supporting documentation, and mechanisms of notification and final determinations on the IRF QRP Web site this spring at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html*. We invite public comment on the proposed procedures for reconsideration and appeals.

G. Proposed Policy for Granting of a Waiver of the IRF QRP Data Submission Requirements in Case of Disaster or Extraordinary Circumstances

Our experience with other quality reporting programs has shown that there are times when providers are unable to submit quality data due to the occurrence of extraordinary circumstances beyond their control (for example, natural or man-made disasters). We define a ''disaster'' as any natural or man-made catastrophe which causes damages of sufficient severity and magnitude to partially or completely destroy or delay access to medical records and associated documentation. Natural disasters could include events such as hurricanes, tornadoes, earthquakes, volcanic eruptions, fires, mudslides, snowstorms, and tsunamis. Man-made disasters could include such events as terrorist attacks, bombings, floods caused by man-made actions, civil disorders, and explosions. A disaster may be widespread or impact multiple structures or be isolated and impact a single site only.

In certain instances of either natural or man-made disasters, an IRF may have the ability to conduct a full patient assessment, and record and save the associated data either during or before the occurrence of an extraordinary event. In this case, the extraordinary event has not caused the facility's data files to be destroyed, but it could hinder the IRF's ability to meet the quality reporting program's data submission deadlines. In this scenario, the IRF would potentially have the ability to report the data at a later date, after the emergency circumstances have subsided. In such cases, a temporary

waiver of the IRF duty to report quality measure data may be appropriate.

In other circumstances of natural or man-made disaster, an IRF may not have had the ability to conduct a full patient assessment, and record and save the associated data before the occurrence of an extraordinary event. In such a scenario, the facility does not have data to submit to CMS as a result of the extraordinary event. We believe that it is appropriate, in these situations, to grant a full waiver of the reporting requirements.

It is our goal not to penalize IRF providers in these circumstances or to unduly increase their burden during these times. Therefore, we are proposing a process, for payment year 2015 and subsequent years, for IRF providers to request and for CMS to grant waivers with respect to the reporting of quality data when there are extraordinary circumstances beyond the control of the provider. When a waiver is granted, an IRF will not incur payment reduction penalties for failure to comply with the requirements of the IRF QRP.

We are proposing a process that, in the event that an IRF seeks to request a waiver for quality reporting purposes for payment year 2015 and subsequent payment years, the IRF may request a waiver for one or more quarters by submitting a written request to CMS. We are proposing that IRFs compose a letter to CMS that documents the waiver request, with the information described below, and submit the letter to CMS via email to the IRF Help Desk at *IRFQualityQuestions@cms.hhs.gov*. IRFs that have filed a request for an IRF QRP disaster waiver with an IRF–PAI waiver request using the procedure that is described under our regulations at 42 CFR 412.614 can indicate this in their letter to CMS for their request for a waiver for quality reporting purposes.[28]

Note that the subject of the email must read ''Disaster Waiver Request'' and the letter must contain the following information:

- IRF CCN;
- IRF name;
- CEO or CEO-designated personnel contact information including name, telephone number, email address, and mailing address (the address must be a physical address, not a post office box);
- IRF's reason for requesting a waiver;
- Evidence of the impact of extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the IRF believes that it will again be able to submit IRF QRP data and a justification for the proposed date.

We propose that the letter documenting the disaster waiver request be signed by the IRF's CEO, and must be submitted within 30 days of the date that the extraordinary circumstances occurred. Following receipt of the letter, we would: (1) Provide a written acknowledgement, using the contact information provided in the letter, to the CEO or designated contact person, notifying them that the request has been received, and (2) after CMS has made a decision as to whether to grant to waiver request, provide a formal response to the CEO, or designated contact person notifying them of our decision.

This proposal does not preclude CMS from granting waivers to IRFs that have not requested them when we determine that an extraordinary circumstance, such as an act of nature, affects an entire region or locale. If we make the determination to grant a waiver to IRFs in a region or locale, we propose to communicate this decision through routine communication channels to IRFs and vendors, including but not limited to issuing memos, emails, and notices on *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html.*

We invite public comment on this proposal.

H. Public Display of Data Quality Measures for the IRF QRP Program

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) also requires procedures to ensure that each IRF provider has the opportunity to review that data that is to be made public with respect to its facility, prior to such data being made public. Section 1886(j)(7)(E) of the Act requires CMS to report quality measures that relate to services furnished in IRFs on CMS' Web site.

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 include related proposals in future rule making. We welcome public comments on what we should consider when developing future proposals related to public reporting.

I. Method for Applying the Reduction to the FY 2014 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 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. FY 2014 is to be the first year that the mandated reduction will be applied for IRFs that failed to comply with the data submission requirements during the data collection period October 1, 2012 through December 31, 2012. Thus, in compliance with 1886(j)(7)(A)(i) of the Act, we will apply a 2 percentage point reduction to the applicable FY 2014 market basket increase factor (1.7 percent) in calculating an adjusted FY 2014 standard payment conversion factor to apply to payments for only those IRFs that failed to comply with the data submission requirements. As noted previously, 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 15 shows the calculation of the adjusted FY 2014 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 for the period from October 1, 2012 through December 31, 2012.

[28] *http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol2/pdf/CFR-2011-title42-vol2-sec412-614.pdf.*

TABLE 15—CALCULATIONS TO DETERMINE THE PROPOSED ADJUSTED FY 2014 STANDARD PAYMENT CONVERSION FACTOR FOR IRFS THAT FAILED TO MEET THE QUALITY REPORTING REQUIREMENT

Explanation for adjustment	Calculations	
Standard Payment Conversion Factor for FY 2013		$14,343
Adjusted Market Basket Increase Factor for FY 2014 (2.5 percent), reduced by 0.3 percentage point in accordance with sections 1886(j)(3)(C) and (D) of the Act and a 0.4 percentage point reduction for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act, further reduced by 2 percentage points for IRFs that failed to meet the quality reporting requirement	×	0.99800
Budget Neutrality Factor for the Wage Index and Labor-Related Share	×	1.0011
Budget Neutrality Factor for the Revisions to the CMG Relative Weights	×	1.0000
Budget Neutrality Factor for the Update to the Rural Adjustment Factor	×	1.0030
Budget Neutrality Factor for the Update to the LIP Adjustment Factor	×	1.0174
Budget Neutrality Factor for the Update to the Teaching Status Adjustment Factor	×	0.9966
Proposed Adjusted FY 2014 Standard Payment Conversion Factor	=	$14,573

XIV. 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. 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 proposed rule does not impose any new information collection requirements as outlined in the regulation text. However, this proposed 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. ICRs Regarding IRF QRP

As stated in section XIII. of the preamble of this proposed rule, we have proposed to introduce one new measure for use in the IRF QRP that will require IRF providers to submit new data beginning on October 1, 2014 and which will affect the increase factor for FY 2016. This quality measure is: Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431). We have also proposed to introduce for FY 2017 an All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities. This measure is a claims-based measure that does not require submission of data by IRF providers. For FY 2017, we have proposed to adopt the Percent of Resident or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF#0680) measure. We have also proposed for FY 2017 to change from the use of a non-risk adjusted pressure ulcer measure, in which only numerator and denominator data is collected, to use of the NQF endorsed measure ''Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay)'' (NQF #0678), which is a risk-adjusted measure. Each of these measures will be collected in the manner described below:

1. Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)

In section XIII. of this proposed rule, we are proposing to add the new measure, Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) to the IRF QRP. IRFs will be required to collect data related to the number of healthcare personnel working at a facility who have been vaccinated against the influenza virus during a given influenza vaccination season. The CDC has determined that the influenza vaccination season begins on October 1st (or when the vaccine becomes available) and ends on the following March 31st each year. This measure requires that the provider submit only one report to NHSN after the close of the data collection period each year.

We believe that it has become a common practice for healthcare facilities, including IRFs, to promote vaccination of employees for the influenza virus and to keep records of which of their staff members received this vaccination each year. Therefore, we do not believe that IRFs will incur any additional burden related to the collection of the data for this measure.

We anticipate that it will take approximately 15 minutes to prepare and transmit the required data for this measure to the CDC each year. The reporting of the data for this measure can be done while the provider is logged onto NHSN for the purpose of entering their CAUTI measure data. We believe that this task can be completed by an administrative person such as a Medical Secretary Medical Data Entry Clerk. The average hourly wage for Medical Records or Health Information Technicians is $15.55.[29] We estimate that the annual cost to each IRF for the reporting of the staff influenza measure will be $3.98.[30] The annual cost across the 1161 IRFs in the U.S. that are reporting data to CMS is estimated to be $4,621.[31]

2. All-Cause Unplanned Readmission Measure for 30 Days Post Discharge From Inpatient Rehabilitation Facilities

As stated in section XIII. of this proposed rule, data for this measure will be collected from Medicare claims and therefore will not add any additional reporting burden for IRFs.

[29] According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical Records & Health Information Technician is $15.55. See: *http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

[30] 15 minutes administrative staff time to collect and report staff influenza measure @ $15.55 per hour = $3.98 per IRF per year

[31] At the time of the writing of this rule, there were 1161 IRFs reporting quality data to CMS. ($3.98 per IRF per year × 1161 IRFs in U.S.= $4,621).

1. Percent of Residents or Patients With Pressure Ulcers That Are New or Have Worsened (Short-Stay) (NQF #0678)

In section XIII of this proposed rule, we proposed to adopt the NQF endorsed version of the measure titled ''Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short-Stay)'' (NQF #0678). To support the standardized collection and calculation of this quality measure, we have proposed to modify the current Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI) by replacing the current pressure ulcer items with data elements similar or identical to those collected through the Minimum Data Set 3.0 (MDS 3.0) used in nursing homes. By building upon preexisting resources for data collection and submission, we intend to reduce administrative burden related to data collection and submission. We anticipate that the initial setup and acclimation to pressure ulcer data collection will have already occurred with the adoption of the Pressure Ulcer measure for the IRF QRP for the FY 2014 payment determination. Therefore, we believe the transition to reporting additional data elements for this measure will be less burdensome.

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 estimate that it will take approximately 10 minutes of time by the RN to perform the admission pressure ulcer assessment. We further estimate that it will take an additional 15 minutes of time to complete the discharge pressure ulcer assessment. We expect that during these time periods, the RN would be engaged in the collection of data for the purpose of the IRF QRP and would not be engaged in the performance of routine patient care.

We estimate that there are 359,000 IRF–PAI submissions per year [32] and that there are 1161 IRFs in the U.S. reporting quality data to CMS. Based on these figures, we estimate that each IRF will submit approximately 309 IRF–PAIs per year or 26 IRF–PAIs per month.[33]Assuming that each IRF–PAI submission requires 25 minutes of time by an RN at an average hourly wage of $33.23,[34] the yearly cost to each IRF would be $4,278.36 [35] and the annualized cost across all IRFs would be $4,967,176.[36]

We also expect 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 into their electronic health record (EHR) system and/or the CMS JIRVEN program. We estimate that this data entry task will take no more than 3 minutes per each IRF–PAI record or 15.45 hours per each IRF annually or 17,937 hours across all IRFs. As noted above, the average hourly wage for a Medical Records & Health Information Technician is $15.55. As we noted above, there are approximately 359,000 IRF–PAI submissions per year and 1161 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 record is $278,930. We further estimate the average yearly cost to each individual IRF to be $240.25.

We estimate 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 144.20 hours for each individual IRF and 167,416 hours across all IRFs. The total estimated annualized cost for collection and submission of pressure ulcer data is $4,518.61 for each IRF and $5,246,106 across all IRFs. We estimate the cost for each pressure ulcer submission to be $14.61.

We are proposing to revise the IRF–PAI instrument to include the data set associated with this measure.

2. Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)

In section XIII. of the of this proposed rule, we have proposed to add the measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680) to the IRF QRP. We have further proposed to add a new set of standardized data elements now used in the MDS 3.0 to the IRF–PAI to collect the data required for this measure.

As noted above, 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. By building upon preexisting resources for data collection and submission, we intend to reduce administrative burden related to data collection and submission. We anticipate that the initial setup and acclimation to data collection through the IRF–PAI for purposes of reporting of IRF quality measure data will have already occurred with the adoption of the Pressure Ulcer measure for the IRF QRP for the FY 2014 payment determination. Therefore, we believe the transition to reporting an additional measure via the IRF–PAI may be less burdensome.

We estimate that completion of the patient influenza measure item set will take approximately 5 minutes to complete. The patient influenza item set consists of three items (questions). Each item is straightforward and does not require physical assessment for completion. We estimate that it will take approximately 0.7 minutes to complete each item, or 2.1 minutes to complete the entire item set. 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 1.6 minutes per items or a total of 5 minutes to complete the item set.

IRF staff will be required to perform a full influenza assessment only during the influenza vaccination season. The CDC defines that influenza vaccination season as the time period from October 1st (or when the vaccine becomes available) through March 31 each year. From April 1st through September 30th, IRFs are not required to perform full influenza screening and may skip to the next item set after checking the selection which indicates that the patient's IRF stay occurred outside of the influenza vaccination season. Our time estimate reflects the averaged amount of time necessary to complete the influenza item set both during and outside the influenza vaccination season.

We anticipate that the patient influenza item set will be completed by a clinician such an RN, while completing the Quality indicator section of the IRF–PAI. It is most appropriate for an RN to complete the influenza item set because it involves performing

[32] MedPAC, A Data Book: Health Care Spending and the Medicare Program (June 2012), *http://www.medpac.gov/chapters/Jun12DataBookSec8.pdf.*

[33] 359,000 IRF–PAIs per all IRFs per year/1161 IRFs in U.S. = 309 IRF–PAIs per each IRF per year.

309 IRF–PAI reports per IRF per year/12 months per year = 26 IRF–PAI reports per each IRF per year.

[34] According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Registered Nurse is $33.23. (See *http://www.bls.gov/oes/2011/may/oes291111.htm*) .

[35] 25 minutes × 309 IRF–PAI assessments per each IRF per year = 7,725 minutes per each IRF per year.

7,725 minutes per each IRF per year/60 minutes per hour = 128.75 hours per each IRF per year.

128.75 hours per year × $33.23 per hour = $4,278.36 nursing wages per each IRF per year.

[36] $4,278.36 × 1161 IRF providers = $4,967,176 per all IRFs per year.

a skilled assessment to determine, from a patient' records, whether the patient has received a vaccination and, if not, to discuss with the patient any medications or other related topics such as medication allergies, other vaccinations that the patient may have had, and any contraindications that might exist for receiving the influenza vaccination. The nurse has knowledge and experience to determine the relevance of this information to the patient influenza items and also determine if the patient should be given the influenza vaccination.

As noted above, we estimate that it will take approximately 5 minutes to complete the patient influenza measure item set. We have noted above that there are approximately 359,000IRF–PAIs completed annually across all 1161 IRFs that report IRF quality data to CMS. This breaks down to approximately 309 IRF–PAIs completed by each IRF yearly.[37] We estimate that the annual time burden for reporting the patient influenza vaccination measure data is 29,896 hours across all IRFs in the U.S. and 26 hours for each individual IRF. According to the U.S. Bureau of Labor, the hourly wage for a Registered Nurse is $33.23. 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 $993,433. We further estimate the cost for each individual IRF to be $855.67.

B. ICRs Regarding Non-Quality Related Proposed Changes to the IRF–PAI

We propose to revise several items on the IRF–PAI to provide greater clarity for providers. The proposed changes include updating several items regarding the response options available to providers. Additionally, we are proposing to remove several items that we believe are unnecessary for providers to continue documenting on the IRF–PAI since those items are already being documented in the patients' medical record. We are also proposing to add several items, such as a signature page, to fulfill providers' request to have an organized way to document who has assessed the patient and when that assessment took place. We do not estimate any additional burden for IRFs to complete the IRF–PAI as a result of these proposals. We estimate the time that will be needed to complete the new non-quality related proposed items, equals the time that was needed to complete the previous non-quality related items. When the original burden estimates were completed for the IRF–PAI, we estimated that the proposed deletion of the non-quality related items would take approximately 3 minutes to complete. Thus, removing these items the IRF–PAI would decrease the total estimated burden of completing the non-quality related portions of the IRF–PAI by 3 minutes. However, we estimate that it will take about 3 minutes to complete the new non-quality related items that we are proposing to add. Therefore, we estimate no net change in the amount of time associated with completing the non-quality related portions of the IRF–PAI and that the burden for completing these portions of the IRF–PAI will not change.

We will be submitting a revision to the current IRF–PAI collection of information approval under (OMB control number 0938–0842) for OMB review and approval.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS–1448–P,

Fax: (202) 395–6974; or

Email: *OIRA_submission@omb.eop.gov.*

XV. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XV. Response to Comments

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XVI. Regulatory Impact Analysis

A. Statement of Need

This proposed rule updates the IRF prospective payment rates for FY 2014 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 proposes some policy changes within the statutory discretion afforded to the Secretary under section 1886(j) of the Act. We propose to revise the list of diagnosis codes that are eligible under the ''60 percent rule,'' update the IRF facility-level adjustment factors, revise sections of the Inpatient Rehabilitation Facility-Patient Assessment Instrument, revise requirements for acute care hospitals that have IRF units, clarify the IRF regulation text regarding limitation of review, and revise and update quality measures under the IRF quality reporting program. We believe that the proposed policy changes would enhance the clarity, accuracy, and fairness of the IRF PPS.

B. Overall Impacts

We have examined the impacts of this proposed 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

[37] 359,000 IRF–PAI reports per all IRFs per year/ 1161 IRFs in U.S. = 309 IRF–PAI reports per each IRF per year.

(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 proposed rule with economically significant effects ($100 million or more in any one year). We estimate the total impact of the proposed policy updates described in this proposed rule by comparing the estimated payments in FY 2014 with those in FY 2013. This analysis results in an estimated $150 million increase for FY 2014 IRF PPS payments. As a result, this proposed 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.

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 $34.5 million in any 1 year, 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 1,200 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 16, we estimate that the net revenue impact of this proposed rule on all IRFs is to increase estimated payments by approximately 2.0 percent. However, we find that certain categories of IRF providers would be expected to experience revenue impacts in the 3 to 5 percent range. We estimate a 4.3 percent overall impact for teaching IRFs with resident to average daily census ratios of 10 to 19 percent, a 9.3 percent overall impact for teaching IRFs with a resident to average daily census ratio greater than 19 percent, and a 3.5 percent overall impact for IRFs with a DSH patient percentage of 0 percent. As a result, we anticipate this proposed rule would have a positive impact on a substantial number of small entities. Medicare fiscal intermediaries, Medicare Administrative Contractors, and carriers 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 603 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 proposed rule would not have a significant impact (not greater than 3 percent) on rural hospitals based on the data of the 167 rural units and 18 rural hospitals in our database of 1,132 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 one year of $100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold level is approximately $141 million. This proposed 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 proposed 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 proposed rule sets forth proposed policy changes and updates to the IRF PPS rates contained in the FY 2013 notice (77 FR 44618). Specifically, this proposed rule proposes updates to the CMG relative weights and average length of stay values, the facility-level adjustment factors, the wage index, and the outlier threshold for high-cost cases. This proposed rule also applies a productivity adjustment to the FY 2014 RPL market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.3 percentage point reduction to the FY 2014 RPL market basket increase factor in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(ii) of the Act. Further, this proposed rule contains proposed changes to the list of ICD–9–CM codes that are used in the 60 percent rule presumptive methodology and, in section XII of this rule. discusses the first implementation (in FY 2014) 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 proposed changes and updates described in this proposed rule would be a net estimated increase of $150 million in payments to IRF providers. This estimate does not include the estimated impacts of the proposed changes to the list of ICD–9–CM codes that are used in the 60 percent rule presumptive compliance (as discussed below) or the estimated impacts of the implementation (in FY 2014) 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 below). The impact analysis in Table 16 of this proposed rule represents the projected effects of the proposed updates to IRF PPS payments for FY 2014 compared with the estimated IRF PPS payments in FY 2013. 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 2014, we are proposing standard annual revisions described in this proposed 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 2014 RPL market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and a 0.3 percentage point reduction to the FY 2014 RPL market basket increase factor in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(ii) of the Act. We estimate the total increase in payments to IRFs in FY 2014, relative to FY 2013, would be approximately $150 million.

This estimate is derived from the application of the FY 2014 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 0.3 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(ii) of the Act, which yields an estimated increase in aggregate payments to IRFs of $135 million. Furthermore, there is an additional estimated $15 million increase in aggregate payments to IRFs due to the proposed update to the outlier threshold amount. Outlier payments are estimated to increase under this proposal from approximately 2.8 percent in FY 2013 to 3.0 percent in FY 2014. Therefore, summed together, we estimate that these updates will result in a net increase in estimated payments of $150 million from FY 2013 to FY 2014.

The effects of the proposed updates that impact IRF PPS payment rates are shown in Table 16. The following proposed updates that affect the IRF PPS payment rates are discussed separately below:

- The effects of the proposed update to the outlier threshold amount, from approximately 2.8 percent to 3.0 percent of total estimated payments for FY 2014, consistent with section 1886(j)(4) of the Act.
- The effects of the proposed 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 0.3 percentage point reduction in accordance with sections 1886(j)(3)(C) and (D) of the Act.
- The effects of applying the proposed budget-neutral labor-related share and wage index adjustment, as required under section 1886(j)(6) of the Act.
- The effects of the proposed 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 effects of the proposed updates to the Rural, LIP, and Teaching Status adjustment factors, using an updated methodology.
- The total change in estimated payments based on the proposed FY 2014 payment changes relative to the estimated FY 2013 payments.

2. Description of Table 16

Table 16 categorizes IRFs by geographic location, including urban or rural location, and location with respect to 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 16 shows the overall impact on the 1,132 IRFs included in the analysis.

The next 12 rows of Table 16 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 947 IRFs located in urban areas included in our analysis. Among these, there are 731 IRF units of hospitals located in urban areas and 216 freestanding IRF hospitals located in urban areas. There are 185 IRFs located in rural areas included in our analysis. Among these, there are 167 IRF units of hospitals located in rural areas and 18 freestanding IRF hospitals located in rural areas. There are 299 for-profit IRFs. Among these, there are 260 IRFs in urban areas and 39 IRFs in rural areas. There are 685 non-profit IRFs. Among these, there are 570 urban IRFs and 115 rural IRFs. There are 148 government-owned IRFs. Among these, there are 117 urban IRFs and 31 rural IRFs.

The remaining four parts of Table 16 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 with respect to their location within a particular one of the nine Census geographic regions. Second, IRFs located in rural areas are categorized with respect to 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 proposed policy described in this proposed rule to the facility categories listed above are shown in the columns of Table 16. 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 2012 analysis file.
- Column (3) shows the number of cases in each category in our FY 2012 analysis file.
- Column (4) shows the estimated effect of the proposed adjustment to the outlier threshold amount.
- Column (5) shows the estimated effect of the proposed 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 0.3 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(ii) of the Act.

• Column (6) shows the estimated effect of the proposed update to the IRF labor-related share and wage index, in a budget neutral manner.

• Column (7) shows the estimated effect of the proposed update to the CMG relative weights and average length of stay values, in a budget neutral manner.

• Column (8) shows the estimated effect of the proposed update to the facility adjustment factors using an updated methodology, in a budget neutral manner.

• Column (9) compares our estimates of the payments per discharge, incorporating all of the proposed policies reflected in this proposed rule for FY 2014 to our estimates of payments per discharge in FY 2013.

The average estimated increase for all IRFs is approximately 2.0 percent. This estimated net increase includes the effects of the proposed RPL market basket increase factor for FY 2014 of 2.5 percent, reduced by a productivity adjustment of 0.4 percentage point in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, and further reduced by 0.3 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and (D)(ii) of the Act. It also includes the approximate 0.2 percent overall estimated increase in estimated IRF outlier payments from the proposed update to the outlier threshold amount. Since we are making the proposed updates to the IRF wage index, the facility-level adjustments, and the CMG relative weights in a budget-neutral manner, they would not be expected to affect total estimated IRF payments in the aggregate. However, as described in more detail in each section, they would be expected to affect the estimated distribution of payments among providers.

TABLE 16—IRF IMPACT TABLE FOR FY 2014

[Columns 4–9 in %]

Facility classification	Number of IRFs	Number of cases	Outlier	Adjusted market basket increase factor for FY 2014 [1]	FY 2014 CBSA wage index and labor-share	CMG	Facility adjust	Total percent change
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Total	1,132	380,988	0.2	1.8	0.0	0.0	0.0	2.0
Urban unit	731	180,061	0.3	1.8	0.0	0.0	0.2	2.5
Rural unit	167	26,894	0.2	1.8	0.1	0.1	−2.8	−0.7
Urban hospital	216	168,159	0.1	1.8	−0.1	0.0	0.3	2.1
Rural hospital	18	5,874	0.1	1.8	−0.2	−0.1	−3.4	−1.9
Urban For-Profit	260	142,026	0.1	1.8	−0.2	0.0	0.3	2.0
Rural For-Profit	39	8,184	0.1	1.8	0.0	0.0	−3.3	−1.4
Urban Non-Profit	570	177,533	0.3	1.8	0.2	0.0	0.3	2.5
Rural Non-Profit	115	19,523	0.2	1.8	0.0	0.0	−2.8	−0.8
Urban Government	117	28,661	0.3	1.8	−0.2	0.0	0.3	2.3
Rural Government	31	5,061	0.3	1.8	0.1	0.1	−3.0	−0.7
Urban	947	348,220	0.2	1.8	0.0	0.0	0.3	2.3
Rural	185	32,768	0.2	1.8	0.0	0.0	−2.9	−0.9
Urban by region [2]								
Urban New England	31	16,756	0.1	1.8	0.8	0.0	0.1	2.7
Urban Middle Atlantic	140	59,219	0.2	1.8	0.0	0.0	0.7	2.7
Urban South Atlantic	130	62,331	0.1	1.8	−0.3	0.0	0.1	1.8
Urban East North Central	182	52,383	0.3	1.8	0.2	0.0	0.6	2.9
Urban East South Central	49	24,405	0.1	1.8	−0.8	0.0	0.5	1.6
Urban West North Central	73	17,946	0.2	1.8	0.5	0.0	0.0	2.5
Urban West South Central	171	67,357	0.2	1.8	−0.1	0.0	0.4	2.3
Urban Mountain	72	23,318	0.3	1.8	−0.5	0.0	0.2	1.7
Urban Pacific	99	24,505	0.4	1.8	0.7	0.0	−0.8	2.1
Rural by region [2]								
Rural New England	6	1,395	0.4	1.8	−0.4	−0.1	−2.1	−0.4
Rural Middle Atlantic	15	2,702	0.2	1.8	−0.3	0.0	−2.6	−0.9
Rural South Atlantic	24	5,546	0.1	1.8	0.0	0.1	−2.9	−0.9
Rural East North Central	32	5,576	0.2	1.8	0.3	0.0	−2.8	−0.5
Rural East South Central	22	3,834	0.2	1.8	0.0	0.1	−3.2	−1.2
Rural West North Central	27	3,624	0.3	1.8	−0.7	0.0	−2.7	−1.4
Rural West South Central	48	9,056	0.2	1.8	0.3	0.0	−3.5	−1.3
Rural Mountain	7	660	0.4	1.8	0.3	0.2	−2.0	0.6
Rural Pacific	4	375	0.8	1.8	0.1	−0.1	−1.3	1.3
Teaching Status								
Non-teaching	1,015	332,827	0.2	1.8	0.0	0.0	−0.2	1.8
Resident to ADC less than 10%	68	32,835	0.2	1.8	0.1	0.0	0.6	2.7
Resident to ADC 10%–19%	37	13,743	0.3	1.8	0.1	0.0	2.1	4.3

TABLE 16—IRF IMPACT TABLE FOR FY 2014—Continued

[Columns 4–9 in %]

Facility classification	Number of IRFs	Number of cases	Outlier	Adjusted market basket increase factor for FY 2014 [1]	FY 2014 CBSA wage index and labor-share	CMG	Facility adjust	Total percent change
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Resident to ADC greater than 19%	12	1,583	0.2	1.8	0.4	0.0	6.7	9.3
Disproportionate Share Patient Percentage (DSH PP)								
DSH PP = 0%	39	7,929	0.8	1.8	0.2	0.0	0.7	3.5
DSH PP less than 5%	193	64,712	0.2	1.8	0.0	0.0	0.9	2.8
DSH PP 5%–10%	323	122,318	0.1	1.8	−0.1	0.0	0.4	2.3
DSH PP 10%–20%	349	125,863	0.2	1.8	0.1	0.0	0.0	2.0
DSH PP greater than 20%	228	60,166	0.3	1.8	0.0	0.0	−1.3	0.7

[1] This column reflects the impact of the RPL market basket increase factor for FY 2014 of 1.8 percent, which includes a market basket update of 2.5 percent, a 0.3 percentage point reduction in accordance with sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(ii) of the Act and a 0.4 percentage point reduction for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act.

[2] A map of states that comprise the 9 geographic regions can be found at (*http://www.census.gov/geo/www/us_regdiv.pdf.*).

3. Impact of the Proposed Update to the Outlier Threshold Amount

The proposed outlier threshold adjustment is presented in column 4 of Table 16. In the FY 2013 IRF PPS notice (77 FR 44618), we used FY 2011 IRF claims data (the best, most complete data available at that time) to set the outlier threshold amount for FY 2013 so that estimated outlier payments would equal 3 percent of total estimated payments for FY 2013.

For this proposed rule, we are proposing to update our analysis using FY 2012 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 2013. Thus, we are proposing to adjust the outlier threshold amount in this proposed rule to set total estimated outlier payments equal to 3 percent of total estimated payments in FY 2014. The estimated change in total IRF payments for FY 2014, 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 proposed outlier adjustment update (as shown in column 4 of Table 16) 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 0.8 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 Proposed Market Basket Update to the IRF PPS Payment Rates

The proposed market basket update to the IRF PPS payment rates is presented in column 5 of Table 16. In the aggregate the proposed update would result in a net 1.8 percent increase in overall estimated payments to IRFs. This net increase reflects the estimated RPL market basket increase factor for FY 2014 of 2.5 percent, reduced by the 0.3 percentage point in accordance with sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(ii) of the Act, and further reduced by a 0.4 percentage point productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act.

5. Impact of the Proposed CBSA Wage Index and Labor-Related Share

In column 6 of Table 16, we present the effects of the proposed budget neutral update of the wage index and labor-related share. The proposed 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 V.C. of this proposed rule, we propose to decrease the labor-related share from 69.881 percent in FY 2013 to 69.658 percent in FY 2014.

In the aggregate, since these proposed 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 proposed updates would affect overall estimated payments to IRFs. However, we estimate that these proposed updates would have small distributional effects. For example, we estimate the largest increase in payments from the proposed update to the CBSA wage index and labor-related share of 0.8 percent for urban IRFs in the New England region. We estimate the largest decrease in payments from the update to the CBSA wage index and labor-related share to be a 0.8 percent decrease for urban IRFs in the East South Central region.

6. Impact of the Proposed Update to the CMG Relative Weights and Average Length of Stay Values.

In column 7 of Table 16, we present the effects of the proposed budget neutral update of the CMG relative weights and average length of stay values. In the aggregate, we do not estimate that these proposed updates would affect overall estimated payments to IRFs. However, we would expect these proposed update to have small distributional effects. Freestanding rural hospitals will see a 0.1 decrease in payments as a result of these updates. The rural areas affected are New England and Pacific. The largest estimated increase in payments as a result of these updates is a 0.2 increase in the Mountain region.

7. Impact of the Proposed Updates to the Facility-Level Adjustments

In column 8 of Table 16, we present the effects of the proposed budget neutral updates to the IRF facility-level adjustment factors (the rural, LIP, and teaching status adjustment factors) for FY 2014. In the aggregate, we do not estimate that these proposed updates

would affect overall estimated payments to IRFs. However, we estimate that these proposed updates would have distributional effects, as shown in Table 16. The largest estimated decrease in payments as a result of these proposed updates is a 3.5 percent decrease to rural IRFs in the West South Central region. The largest estimated increase in payments as a result of these proposed updates is a 6.7 percent increase for teaching IRFs with a resident to average daily census ratio greater than 19 percent.

8. Impact of the Proposed Refinements to the Presumptive Compliance Criteria Methodology

As discussed in section VII. of this proposed rule, we are proposing changes to the list of ICD–9–CM codes available to meet the presumptive compliance criteria. We believe that these proposed changes would affect all 1,132 IRFs, as these facilities would need to change their coding practices to continue to meet the 60 percent compliance percentage using the presumptive methodology.

We estimate that the financial impact, in the absence of any behavioral responses to these proposed changes on the part of providers, would be a decrease of 6.9 percent (or $520 million) in overall estimated payments to IRFs. However, we believe that IRFs will be able to improve the specificity of their coding practices, alter their admitting practices, meet the 60 percent compliance threshold under medical review, and make other modifications to their operations to continue to meet the 60 percent compliance threshold.

For example, we estimate that about 92 percent of the IRF cases that would potentially be affected by the proposed revisions to the presumptive methodology codes are affected by the removal of the non-specific codes. However, we have been careful to propose removal only of those non-specific codes for which more specific codes for the same conditions will remain on the list of codes that meet the presumptive methodology. Thus, in all of these cases, we believe that the IRF will be able to switch to a more specific code for the same condition, leaving the IRF's admission practices and classification status unaffected. However, we welcome comments on whether there are any particular non-specific codes or situations in which switching to a more specific code would be unusually difficult for an IRF.

Fewer than 1 percent of the cases that we estimate would be affected by the proposed revisions are affected by the Unilateral Upper Extremity Amputation codes, the Congenital Anomaly codes, and the Miscellaneous codes combined. Thus, we do not estimate that the proposed removal of these code groups would have a significant effect on IRF admission or coding practices, or classification status. However, we welcome comments on whether individual IRFs may specialize in any of these conditions and might therefore be disproportionately affected by these proposed revisions.

Finally, approximately 7 percent of the cases that we estimate would be affected by the proposed revisions involve arthritis diagnoses. We estimate that the proposed revisions in this category would have the largest potential effects on providers because, by the very nature of these revisions, IRFs would not have another arthritis code on the list to code instead. We estimate that about 14 percent of all IRF cases are coded with the arthritis codes that we propose to remove from the list, and in 11 percent of these cases, the arthritis code is the only code that would qualify the patient as meeting the 60 percent rule requirements. However, for the arthritis category of codes, we estimate that most of these cases will still be found to meet the 60 percent rule requirements under medical review, so we estimate that these proposed revisions will lead to few if any IRF declassifications. However, we welcome comments on whether there are any reasons to believe that the arthritis cases may not generally be found to count towards the 60 percent rule requirements under medical review.

Historically, we have seen that IRFs adapt quickly to changes in the 60 percent rule, as evidenced by the rapid response to changes over time in the compliance threshold. Thus, we have every reason to believe that they will adapt quickly to the proposed changes to the presumptive methodology list. In addition, the proposed changes would not affect how many patients would ultimately be shown to meet the 60 percent rule criteria on medical review. For these reasons, we believe that our best estimate of the impact on IRFs of these changes is no net change in Medicare reimbursement payments. Instead, IRFs will quickly change their coding practices, admission practices, meet the 60 percent compliance threshold under medical review, and make other changes to their business practice to ensure that they continue to meet the 60 percent rule requirements; although we lack data to more precisely characterize the rule-induced costs, benefits and transfers that would be experienced by IRFs, their patients and other relevant entities, we note that the $520 million estimate appearing earlier in this section represents an upper bound (probably an extreme upper bound) on the costs that would be borne by IRFs.

Should these proposed changes to the 60 percent rule be finalized, we intend to closely monitor provider coding practices to identify whether those patients that we envisioned would be served under the IRF PPS are counting toward the presumptive compliance percentage. We will also monitor whether these proposed changes are having any unintended consequences in terms of limiting access to care.

9. Effects of Proposed Updates to the IRF QRP

In this rule, we are proposing to continue use of the pressure ulcer measure that was adopted in the FY 2012 IRF PPS final rule but have proposed to change this measure for the IRF PPS increase factor for FY 2017, at which time we are proposing to adopt the NQF-endorsed version of this measure. We are further proposing to make revisions to the pressure ulcer items on the IRF–PAI that providers will use to collect data for this measure.

IRFs will incur some financial impact from the use of the pressure ulcer measure item set that will be incorporated into the IRF–PAI. We expect that the admission and discharge pressure ulcer data will be collected by a clinician such as a registered nurse (RN) because the assessment and staging of pressure ulcers requires a high degree of clinical judgment and experience. We estimate that it will take approximately 10 minutes of time by the RN to perform the admission pressure ulcer assessment. We further estimate that it will take 15 minutes of time to complete the discharge pressure ulcer assessment. During these time periods, the RN would be engaged in the collection of data for the purpose of the IRF quality reporting program and would not be performing patient care. An RN or clinician of a similar level of training and expertise should perform the pressure ulcer assessment and record this data on the IRF–PAI.

We believe use of the NQF endorsed pressure ulcer measure will cause IRFs to incur additional annual financial burden in the amount of $4,518.61 and across all IRFs, $5,246,106. This burden is comprised of the clinical and administrative wages. The clinical wages are based on an average hourly

wage rate of $33.23.[38] We estimate that there are 359,000 IRF–PAI submissions per year [39] and that there are 1161 IRFs in the U.S. that have reported quality data to CMS. Based on these figures, we estimate that each IRF will submit approximately 309 IRF–PAIs per year or 25.75 IRF–PAIs per month.[40] Assuming that each IRF–PAI submission requires 25 minutes of time by an RN at an average hourly wage of $33.23, the yearly cost to each IRF would be $4,278.36 [41] and the annualized cost across all IRFs would be $4,967,176.[42] To calculate the total amount of administrative staff wages incurred, we estimate that this data entry task will take no more than 3 minutes per each IRF–PAI record or 15.45 hours per each IRF annually or 17,937 hours across all IRFs. According to the U.S. Bureau of Labor, the average hourly wage for Administrative Assistants is $15.55. As noted above, we have estimated that there are approximately 359,000 IRF–PAI submissions per year and 1161 IRFs in the U.S. that are reporting quality data to CMS. Given this wage information, the estimated total annual cost across all IRFs for the time required for entry of pressure ulcer data into the IRF–PAI record is $278,930. We further estimate the average yearly cost to each IRF to be $240.25.

We are also proposing to add 3 new quality measures to the IRF QRP. These proposed measures include: (1) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680), which will affect the FY 2017 increase factor; (2) Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431), which will affect the FY 2016 increase factor; and (3) an All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from Inpatient Rehabilitation Facilities, which will affect the FY 2017 increase factor. We discuss the impact of each measure upon IRFs below.

We have proposed that IRFs will submit their data for the patient influenza measure (NQF #0680) on the IRF–PAI. We have further proposed to add a new data item set consisting of 3 items to the IRF–PAI to collect the data for this measure. IRF staff will be required to perform a full influenza assessment only during the influenza vaccination season, which has been defined by the CDC as the time period from October 1st (or when the vaccine becomes available) through March 31 each year. From April 1st through September 30th, IRFs are not required to perform a full influenza screening. Our time estimate reflects the averaged amount of time necessary to complete the influenza item set both during and outside the influenza vaccination season.

We believe that it will be most appropriate for a clinician, such as an RN, to complete the influenza items because this assessment requires clinical judgment and knowledge of vaccinations. An administrative employee, such as a medical data entry clerk or administrative assistant would not have this level of knowledge. We do not believe that IRFs will require additional time by administrative staff to encode and transmit this data to CMS, because submission of an IRF–PAI for each patient is already required as a condition for payment.

We estimate that it will take approximately 5 minutes to complete the patient influenza measure item set. According to MedPAC, there are approximately 359,000 [43] IRF–PAIs completed annually across 1161 IRFs that reported quality data to CMS. This breaks down to approximately 309 IRF–PAIs completed by each IRF yearly. We estimate that the annual time burden for reporting the patient influenza vaccination measure data is 29,896 hours across all IRFs in the U.S. and 25.75 hours for each individual IRF. According to the U.S. Bureau of Labor, the hourly wage for a Registered Nurse is $33.23. The estimated annual cost across all IRFs in the U.S. for the submission of the patient influenza measure data is $993,433 and $855.67 for each individual IRF.

IRFs will submit their data for the staff immunization measure (NQF #0431) to the CDC's healthcare acquired (HAI) surveillance Web site known as NHSN. Data collection for this measure is only required from October 1st (or when the vaccine becomes available) through March 31st each year, during which IRFs will be required to keep records of which staff members receive the influenza vaccination. However, IRFs are required to make one report to NHSN after the close of the reporting period on March 31st, by May 15th of each year. We do not believe that IRFs will incur any new burden associated with the collection of data during the influenza vaccination season. We believe that most IRFs already keep records related to the influenza vaccination of their staff because this impacts on many aspects of their business, including but not limited to staff absences, and transmission of illness to other staff and patients.

We estimate that it will take each IRF approximately 15 minutes of time once per year to gather the data that was collected during the influenza vaccinations season, and prepare to make their report to NHSN. We do not estimate that it will take IRFs additional time to input their data into NHSN, once they have logged onto the system for the purpose of submitting their monthly CAUTI report. We believe that this task can be completed by an administrative person such as a Medical Secretary Medical Data Entry Clerk. As noted above, the average hourly wage for Medical Records or Health Information Technicians is $15.55.[44] We estimate that the average yearly cost to each IRF for the reporting of this measure will be $3.98 [45] and the cost across all IRFs will be $4,621.[46]

The proposed readmission measure is a claims based measure and, therefore, IRFs are not required to submit any data for this measure. We do not anticipate that IRFs will be impacted by any financial or time burdens as a result of the use of this measure for the IRF QRP.

The IRF QRP was established under section 3004 of the Affordable Care Act (which added Section 1886(j)(7)(A)(i) to the Act). Section 1886(j)(7)(A)(i) requires the reduction of the applicable IRF PPS increase factor, as previously modified under section 1886(j)(3)(D) of the Act, by 2 percentage points for any IRFs that fail to submit data to the Secretary in accordance with

[38] According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Registered Nurse is $33.23. (See *http://www.bls.gov/oes/2011/may/oes291111.htm*).

[39] MedPAC, A Data Book: Health Care Spending and the Medicare Program (June 2012), *http://www.medpac.gov/chapters/Jun12DataBookSec8.pdf.*

[40] 359,000 IRF–PAI reports per all IRFs per year/1161 IRFs in U.S. = 309 IRF–PAI reports per each IRF per year. 309 IRF–PAI reports per IRF per year/12 months per year = 26 IRF–PAI reports per each IRF per year.

[41] 25 minutes × 309 IRF–PAI assessments per each IRF per year = 7,725 minutes per each IRF per year. 7,725 minutes per each IRF per year/60 minutes per hour = 128.75 hours per each IRF per year. 128.75 hours per year × $33.23 per hour = $4,278.36 nursing wages per each IRF per year.

[42] $4,278.36 × 1161 IRF providers = $4,967,176 per all IRFs per year.

[43] MedPAC, A Data Book: Health Care Spending and the Medicare Program (June 2012), Page 129 ().(*http://www.medpac.gov/chapters/Jun12DataBookSec8.pdf*).

[44] According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical Records & Health Information Technician is $15.55. See: *http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

[45] 15 minutes Admin staff time to collect and report staff influenza measure @ $15.55 per hour = $3.98 per IRF per year.

[46] $3.98 per IRF per year × 1161 IRFs in U.S.= $4,621.

requirements established by the Secretary for that fiscal year.

Over the past 18 months, we have received a great deal of positive feedback from IRFs about the IRF QRP, and overall, IRFs have been very receptive to the introduction of the ACA 3004 IRF QRP into the IRF setting. The IRF provider community has shared many suggestions and ideas related to the IRF QRP. Outreach activities, such as a one day in-person training, and six open door forums were well attended. Given the amount of positive feedback and willingness to participate in the IRF QRP that has been demonstrated by IRFs, we anticipate that there will be a relatively small number of IRFs that fail to report the required type and amount of quality data. If finalized, our proposed reconsideration process would allow IRFs that receive an initial finding of non-compliance an opportunity to file a request for reconsideration of this finding.

10. Impact of the Implementation of the 2 Percentage Point Reduction in the Increase Factor for Failure to Meet the IRF Quality Reporting Requirements

As discussed in section XIII. of this proposed rule and in accordance with section 1886(j)(7) of the Act, we will implement a 2 percentage point payment reduction in FY 2014 for IRFs that fail to report the required quality reporting data to us during the first IRF quality reporting period (from October 1, 2012 through December 31, 2012). In section XIII., we discuss how the 2 percentage point payment reduction will be applied. Currently, we cannot estimate the overall financial impacts of the application of this reduction on aggregate IRF PPS payments or on the distribution of IRF PPS payments among providers because we cannot predict the number of or types of IRFs that will fail to report the required quality reporting data. IRFs are currently required to complete the non-quality portions of the IRF–PAI to receive payment for all Medicare fee-for-service admissions. Therefore, we estimate that the number of IRFs that would fail to submit the additional quality reporting data on the IRF–PAI form is very low. Additionally, the Catheter Associated Urinary Tract Infections (CAUTI) quality reporting requirement would require IRFs to register with the National Healthcare Safety Network (NHSN) to submit the required data. At this time, we cannot predict how many IRFs would fail to register.

The official reporting period end date for the first IRF quality reporting period is May 15, 2013. We expect a preliminary report of the IRFs that have failed to report the required data during the first quality reporting period to be developed by mid-June 2013. However, that list could change substantially during the proposed reconsideration process (described in section XIII. of this proposed rule) that would occur between June 2013 and September 2013. Therefore, we intend to closely monitor the effects of this new quality reporting program on IRF providers as we cannot predict the number of, or types of IRFs that would fail to report the required quality reporting data for the first quality reporting period.

D. Alternatives Considered

As stated in section XV.B. of this proposed rule, we estimate that the proposed changes discussed in the rule would result in a significant economic impact on IRFs. The overall impact on all IRFs is an estimated increase in FY 2014 payments of $150 million (2.0 percent), relative to FY 2013. The following is a discussion of the alternatives considered for the proposed IRF PPS updates contained in this proposed 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 2014. However, as noted previously in this proposed rule, section 1886(j)(3)(C)(ii)(I) requires the Secretary to apply a productivity adjustment to the market basket increase factor for FY 2014 and sections 1886(j)(3)(C)(ii)(II) and 1886(j)(3)(D)(ii) of the Act require the Secretary to apply a 0.3 percentage point reduction to the market basket increase factor for FY 2014. Thus, in accordance with section 1886(j)(3)(C) of the Act, we proposed to update IRF federal prospective payments in this proposed rule by 1.8 percent (which equals the 2.5 percent estimated RPL market basket increase factor for FY 2014 reduced by 0.3 percentage points, and further reduced by a 0.4 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 2014. 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 propose 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 maintaining the current facility-level adjustment factors (that is, the rural factor at 18.4 percent, the LIP factor at 0.4613, and teaching status adjustment factor at 0.6876) for an additional year. However, as discussed in more detail in section IV.B. of this proposed rule, our recent research efforts have shown significant differences in cost structures between freestanding IRFs and IRF units of acute care hospitals (and CAHs). We have found that these cost structure differences substantially influence the estimates of the adjustment factors. For this reason, our regression analysis found that the proposed inclusion of the control variable for a facility's status as either a freestanding IRF hospital or an IRF unit of an acute care hospital (or a CAH) would greatly enhance the accuracy of the adjustment factors for FY 2014, as we incorporate updated data. Further, as noted previously, we received comments from an IRF industry association on the FY 2012 IRF PPS proposed rule suggesting this enhancement to the methodology. Thus, we believe that the best approach at this time is to propose to update the facility-level adjustment factors for FY 2014 using this proposed enhancement to the methodology. However, we welcome comments on this approach and on whether or not the facility-level adjustment factors need updating at this time or should be frozen at their current levels for an additional year.

We considered maintaining the existing outlier threshold amount for FY 2014. However, analysis of updated FY 2012 data indicates that estimated outlier payments would be lower than 3 percent of total estimated payments for FY 2013, by approximately 0.2 percent, unless we updated the outlier threshold amount. Consequently, we propose adjusting the outlier threshold amount in this proposed 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 2014.

Finally, we considered maintaining the current list of ICD–9–CM codes used to determine an IRF's compliance with the 60 percent rule under the presumptive methodology, or maintaining some of the categories of codes that we are proposing to remove from the list in this proposed rule. However, we believe that the specific ICD–9–CM code removals that we are

proposing in section VII. of this proposed rule would result in a list that better reflects the 60 percent rule regulations. For example, the proposed removal of the non-specific diagnosis codes (as discussed in section VII. of this proposed rule) is in accordance with the trend toward requiring more specific coding in other Medicare payment settings, such as the IPPS. We believe that the incentives to use more specific codes, whenever possible, will also lead to improvements in the quality of care for patients by providing more detailed information that medical personnel can use to enhance the specificity of patients' care plans. In addition, the proposed removal of the arthritis diagnosis codes (as discussed in section VII. of this proposed rule) would enable CMS to ensure that we only count patients as meeting the 60 percent rule requirements if they have met the necessary severity and prior treatment requirements, information which is not discernible from the ICD–9–CM codes themselves. With respect to the other code categories that we are proposing to remove from the presumptive methodology list, we do not believe that patients who are coded with these codes would typically require treatment in an IRF, as described in more detail in section VII. of this proposed rule. However, we welcome comments on whether there are any specific reasons that we may not have previously considered that would argue for keeping certain of these codes on the presumptive methodology list.

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 17, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. Table 17 provides our best estimate of the increase in Medicare payments under the IRF PPS as a result of the proposed updates presented in this proposed rule based on the data for 1,132 IRFs in our database.

TABLE 17—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2013 IRF PPS FISCAL YEAR TO THE 2014 IRF PPS FISCAL YEAR

Category	Transfers
Annualized Monetized Transfers	$150 million.
From Whom to Whom?	Federal Government to IRF Medicare Providers.
Estimated annualized cost to the federal government for the administration of the IRF quality reporting program.	$2 million. (This cost is attributed to various sources, including but not limited to the CCSQ IRF measure developer contractor and the Division of National Systems).

F. Conclusion

Overall, the estimated payments per discharge for IRFs in FY 2014 are projected to increase by 2.0 percent, compared with the estimated payments in FY 2013, as reflected in column 9 of Table 16. IRF payments per discharge are estimated to increase 2.3 percent in urban areas and decrease 0.9 percent in rural areas, compared with estimated FY 2013 payments. Payments per discharge to rehabilitation units are estimated to increase 2.5 percent in urban areas and decrease 0.7 percent in rural areas. Payments per discharge to freestanding rehabilitation hospitals are estimated to increase 2.1 percent in urban areas and decrease 1.9 percent in rural areas.

Overall, IRFs are estimated to experience a net increase in payments as a result of the proposed policies in this proposed rule. The largest payment increase is estimated to be a 2.9 percent increase for urban IRFs located in the East North Central region. This is due to the large positive effect of the facility adjustment updates for urban IRFs in this region.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as follows:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 continues to read as follows:

Authority: Sections 1102, 1862, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395y, and 1395hh).

■ 2. Section 412.25 is amended by revising paragraph (a)(1)(iii) to read as follows:

§ 412.25 Excluded hospital units: Common requirements.

(a) * * *

(1) * * *

(iii) Unless it is a unit in a critical access hospital, the hospital of which an IRF is a unit must have at least 10 staffed and maintained hospital beds that are not excluded from the inpatient prospective payment system, or at least 1 staffed and maintained hospital bed for every 10 certified inpatient rehabilitation facility beds, whichever number is greater. Otherwise, the IRF will be classified as an IRF hospital, rather than an IRF unit. In the case of an IPF unit, the hospital must have enough beds that are not excluded from the inpatient prospective payment system to permit the provision of adequate cost information, as required by § 413.24(c) of this chapter.

* * * * *

■ 3. Section 412.29 is amended by revising paragraph (d) to read as follows:

§ 412.29 Classification criteria for payment under the inpatient rehabilitation facility prospective payment system.

* * * * *

(d) Have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital program. This procedure must ensure that the preadmission screening for each Medicare Part A fee-for-service patient is reviewed and approved by a rehabilitation physician prior to the patient's admission to the IRF.

* * * * *

■ 4. Section 412.130 is amended by revising paragraphs (a)(1), (a)(2) and (a)(3) to read as follows:

§ 412.130 Retroactive adjustments for incorrectly excluded hospitals and units.

(a) * * *

(1) A hospital that was excluded from the prospective payment systems

specified in § 412.1(a)(1) or paid under the prospective payment system specified in § 412.1(a)(3), as a new rehabilitation hospital for a cost reporting period beginning on or after October 1, 1991 based on a certification under § 412.29(c) of this part regarding the inpatient population the hospital planned to treat during that cost reporting period, if the inpatient population actually treated in the hospital during that cost reporting period did not meet the requirements of § 412.29(b).

(2) A hospital that has a unit excluded from the prospective payment systems specified in § 412.1(a)(1) or paid under the prospective payment system specified in § 412.1(a)(3), as a new rehabilitation unit for a cost reporting period beginning on or after October 1, 1991, based on a certification under § 412.29(c) regarding the inpatient population the hospital planned to treat in that unit during the period, if the inpatient population actually treated in the unit during that cost reporting period did not meet the requirements of § 412.29(b).

(3) A hospital that added new beds to its existing rehabilitation unit for a cost reporting period beginning on or after October 1, 1991 based on a certification under § 412.29(c) regarding the inpatient population the hospital planned to treat in these new beds during that cost reporting period, if the inpatient population actually treated in the new beds during that cost reporting period did not meet the requirements of § 412.29(b).

* * * * *

■ 5. Section 412.630 is revised to read as follows:

§ 412.630 Limitation on review.

Administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, is prohibited with regard to the establishment of the methodology to classify a patient into the case-mix groups and the associated weighting factors, the Federal per discharge payment rates, additional payments for outliers and special payments, and the area wage index.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 16, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: April 25, 2013.

Kathleen Sebelius,

Secretary.

[FR Doc. 2013–10755 Filed 5–2–13; 4:15 pm]

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Part III

Environmental Protection Agency

40 CFR Parts 158 and 161

Data Requirements for Antimicrobial Pesticides; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 158 and 161

[EPA–HQ–OPP–2008–0110; FRL–8886–5]

RIN 2070–AD30

Data Requirements for Antimicrobial Pesticides

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is revising the data requirements for antimicrobial pesticide products to reflect current scientific and regulatory practice, and to provide the regulated community with clearer and transparent information about the data needed to support pesticide registration decisions for antimicrobial products. The updated data requirements also serve to further enhance EPA's ability to make regulatory decisions about the human health, and environmental fate and effects of antimicrobial pesticide products. These revisions are also expected to help protect human health and the environment by providing an up-to-date scientific framework for identifying and assessing the risks of antimicrobial pesticides sold or distributed in the United States.

DATES: This final rule is effective July 8, 2013.

ADDRESSES: The docket for this action, identified under docket identification (ID) number EPA–HQ–OPP–2008–0110, is available at *http://www.regulations.gov* or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in the EPA West 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: Kathryn Boyle, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–6304; email address: *boyle.kathryn@epa.gov,* or contact Scott Drewes, same address: telephone number (703) 347–0107; email address: *drewes.scott@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be affected by this action if you are a producer of pesticide products (NAICS 32532), antifoulants (NAICS 32551), antimicrobial pesticides (NAICS 32561) or wood preservatives (NAICS 32519), importers of such products, or any person or company who seeks to register an antimicrobial, antifoulant coating, ballast water treatment, or wood preservative pesticide or to obtain a tolerance for such a pesticide. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed could also be affected.

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

This action is issued under the authority of sections 2, 3, 4, 5, 10, 12, and 25 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.,* and section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. The data required for antimicrobials (e.g., for registration, reregistration or registration review, experimental use permit (EUP), or tolerance/tolerance exemption) are currently listed in 40 CFR part 161 and, with this final rule, will be listed in 40 CFR part 158.

C. What action is the agency taking?

The Agency is revising and updating the data requirements for antimicrobial pesticides that are currently found in Title 40 of the Code of Federal Regulations (CFR) in part 161, and which are being relocated as revised by this rule to subpart W of part 158. Subpart W sets out data requirements specific to antimicrobial products that are described by the antimicrobial use patterns and use exposure considerations particular to antimicrobials. With the promulgation of part 158, subpart W, EPA is removing part 161, entitled ''Data Requirements for Registration of Antimicrobial Pesticides'' as it is no longer needed.

Antimicrobial pesticides are used to control microbiological contamination in healthcare applications, and deterioration in industrial, commercial, and consumer products. Nearly 60 percent of antimicrobial products are registered as public health products (as defined at FIFRA 2(gg)) to control infectious microorganisms in hospitals and other health care environments. Public health products are intended to control microorganisms infectious to humans in any inanimate environment. The common public health antimicrobial products include sterilants, disinfectants, and sanitizers. Nonpublic health products are sold and distributed for use to control growth of algae, odor-causing bacteria, bacteria which cause spoilage, deterioration or fouling of materials and microorganisms infectious only to animals. Other examples of nonpublic health products include products used in cooling towers, jet fuel, paints, and treatments for textile and paper products. Within this final rule EPA is using the term antimicrobials to collectively refer to antimicrobial pesticides, antifoulant coatings and paints, and wood preservatives. The amendments contained in this final rule, which are discussed in detail in Units IV. through XXII. of this document, change the existing data requirements for antimicrobial pesticides in the following substantive respects:

- By changing some of the existing data requirements, such as a change from conditionally-required to required, a change in the number of test species, or expanding the number of use patterns for which the test is required.
- By adding newly codified data requirements, i.e., data requirements that are not currently identified in 40 CFR part 161, but are considered in current practice on a case-by-case basis.
- By adding new data requirements, i.e., data requirements that have not been required or have rarely been required in current practice on a case-by-case basis, and have not been routinely considered during the Agency's evaluation of the data needed for the purpose of risk assessment.
- By eliminating the requirement for the chronic non-rodent study currently required in 40 CFR part 161.
- By codifying the antimicrobial data requirements as finalized in this rule in 40 CFR part 158, subpart W, and removing the current requirements that appear in 40 CFR part 161.

D. What are the incremental costs and benefits of this action?

The Economic Analysis (EA) of the potential costs and benefits associated with this action, as revised to address comments received on the proposed rule, is contained in a document entitled ''Final Economic Analysis of Changes in Data Requirements for Antimicrobial Pesticides'' (Ref. 1), a copy of which is in the docket, discussed in Unit XXII., and are briefly summarized here.

1. *Estimated costs.* In its analysis, the Agency considered the potential, additional costs for the registration of new antimicrobial pesticides or new uses of currently registered antimicrobial pesticides, as well as the potential, additional costs incurred during the registration review of existing antimicrobial pesticides.

The estimated total annual industry costs of the final rule is expected to be about $19.3 million. The difference between the baseline costs (the existing data requirements that were codified in 1984) and the cost of the Agency's current practices is about $1 million annually. The difference between the baseline costs and the final rule costs, i.e., the incremental costs, is approximately $8.2 million annually assuming an estimated 15 new registrations.

Under the final rule, the average cost per registration action of a new antimicrobial active ingredient is approximately $1 million to $5 million. For existing chemicals, data requirements in part 158, subpart W are relevant to the registration review program, and the average additional cost is estimated to be about $588,000 for wood preservatives, $284,000 for food and indirect food uses, and $260,000 for all other uses. For registration review, the total annual cost is $6.8 million.

EPA also conducted an analysis of the potential impact of this final rule on small entities, which is included in the EA and discussed in Unit XXV.C. In brief, EPA estimates that 500, or approximately 67 percent, of the unique parent companies that constitute the total universe of pesticide antimicrobial registrants, qualify as a small business. When considering both registration review and new registrations, on average each year about 30 small businesses are estimated to incur additional costs under this final rule. EPA estimates that about 23 small firms (almost 5 percent of the 500 small antimicrobial firms) may experience an economic impact of 3 percent or more of gross sales. As discussed later in this document, EPA has concluded, based on this analysis, that this potential impact is not a significant impact on a substantial number of small entities.

2. *Estimated benefits.* In its analysis, EPA provides a qualitative discussion of the benefits, which are not quantifiable in the same monetary terms as the costs. In general, before manufacturers can sell pesticides in the United States, EPA must evaluate the pesticides thoroughly to ensure that they meet Federal safety standards in FIFRA and FFDCA that were established to protect human health and the environment. EPA grants a ''registration'' or license that permits a pesticide's distribution, sale, and use only after the company meets the scientific and regulatory requirements. In evaluating a pesticide registration application, EPA assesses a wide variety of potential human health and environmental effects associated with use of the product. Applicants, or potential registrants, must generate or provide the scientific data necessary to address the identity, composition, potential adverse effects, and environmental fate of each pesticide. The information provided by the data requirements in this final rule allow EPA to evaluate whether an antimicrobial pesticide meets the applicable statutory standards.

Antimicrobials play an important role in public health and safety. While intended to provide health benefits of pathogen control or removal and, in some cases, safety benefits of materials preservation, they also involve risks of potential efficacy failure and exposure of hazards to humans and the environment. Therefore, the effectiveness and proper use of an antimicrobial pesticide is determined by EPA based on its evaluation of specific data that is provided as part of registration and registration review activities.

This final rule will enhance EPA's ability to make sound regulatory decisions and help prevent the registration of pesticide products that may have unreasonable adverse effects on human health and the environment. The Agency believes that having the appropriate data ultimately leads to better risk management decisions, as well as provides the following other benefits:

i. *More refined assessments mean less uncertainty and clearer understanding of actual risks.* For example, EPA's current applicator/user exposure data base is not comprehensive, especially regarding exposures to pesticides in industrial and residential settings. Codifying these data requirements, many of which are currently applied on a case-by-case basis, would allow the Agency to conduct improved exposure assessments for applicators/users. This will benefit workers and consumers by allowing EPA to make better informed regulatory decisions that are neither too stringent nor too lenient.

ii. *Clarity and transparency to regulated community means savings.* The enhanced clarity and transparency of the information presented in part 158, subpart W will reduce uncertainty for applicants in generating and submitting data that is necessary for EPA to be able to make registration decisions based on data-driven risk estimates that use fewer conservative assumptions. Applicants may save time and money by understanding which studies are needed to support the use of their product. Thus, the antimicrobial industry will, along with other partners in the regulated community, attain a better understanding of and can more efficiently participate in the pesticide registration process. This should allow products to enter the market earlier, thereby enabling registration of safer pesticides sooner and potentially reducing risks, as well as increasing profits. The clarity derived from having data requirements specific to antimicrobials may be especially important to small firms and new firms entering the industry who may have less experience than those firms that routinely work with the Agency.

iii. *EPA information assists other communities in assessing pesticide risks.* Scientific, environmental, and health communities find pesticide toxicity information useful to respond to a variety of needs. For example, medical professionals are concerned about the health of patients exposed to pesticides; poison control centers make use of and distribute information on toxicity and treatment associated with poisoning; and scientists use toxicity information to characterize the effects of pesticides and to assess risks of pesticide exposure. Similarly those responsible for protection of nontarget wildlife need reliable information about pesticides and assurance that pesticides do not pose an unreasonable threat. These data requirements will help the scientific, environmental, and health communities by increasing the breadth, quality, and reliability of Agency regulatory decisions by improving their scientific underpinnings.

iv. *Better informed users mean informed risk-reduction choices.* Better regulatory decisions resulting from these data requirements also mean that the label will provide better information on the use of the pesticide. A pesticide label is the user's direction for using pesticides safely and effectively. It contains important information about where to use, or not use, the product, health and safety information that should be read and understood before using a pesticide product, and how to dispose of that product. This benefits users by enhancing their ability to obtain pesticide products appropriate to their needs, and to use and dispose of products in a manner that is safe and environmentally sound.

v. *Recognizes the unique down-the-drain uses associated with antimicrobials.* For antimicrobial

chemicals that go down the drain and eventually reach a waste water treatment plant (WWTP), EPA intends to conduct an assessment of the potential impact of the antimicrobial chemical on the microorganisms in the biological treatment processes of a WWTP and the potential for the antimicrobial chemical to pass through the WWTP in the effluent. The final rule will minimize costs to States and municipalities by ensuring that antimicrobial pesticide products registered under FIFRA don't cause water quality problems or harm treatment facilities.

vi. *A milestone towards the Agency's vision for 21st Century toxicology and new integrated testing strategies.* The Agency's goal is to use 21st Century science to increase the efficiency and effectiveness of our assessment process. This rule is a launching pad for that vision.

II. Background

A. Brief History of Pesticide Data Requirements

EPA's data requirements for pesticides were first published in 1984. Those data requirements were primarily influenced by agricultural uses. Since then, new risk concerns have been identified, and EPA's statutory mandates for pesticide registration under FIFRA and tolerance-setting under the FFDCA were amended in 1996 to require EPA to update the scientific underpinnings of risk assessments. The Agency must now perform more in-depth risk analyses, such as aggregate and cumulative risk assessments.

On October 26, 2007, EPA promulgated final rules updating the data requirements for conventional pesticides (72 FR 60934), and biochemical pesticides and microbial pesticides (72 FR 60988). The rule development process for part 158, subpart W used the updated conventional pesticides data requirements as the starting point while considering the case-by-case data requirement decisions made over the years of registering antimicrobial pesticide products. The following four subparts in part 158, promulgated in 2007, also apply to antimicrobial pesticides (see 40 CFR 158.1):

- Subpart A: General Provisions
- Subpart B: How to Use Data Tables
- Subpart C: Experimental Use Permits
- Subpart D: Product Chemistry

To provide continued regulatory coverage for antimicrobial pesticides until the Agency could promulgate a final regulation for antimicrobial pesticides, the 2007 final rule (72 FR 60251, October 24, 2007) (FRL–8116–2) preserved the original part 158 data requirements (promulgated in 1984) to apply to antimicrobial pesticides by redesignating them as part 161. This final rule finishes the promulgation of a final regulation for antimicrobial pesticides. Accordingly, EPA is also revoking 40 CFR part 161.

B. How To Use the Data Tables

In establishing the data requirements in 1984, EPA adopted a step-wise approach to assist the applicant in determining the data needed to support the registration of a particular product. This approach, which is described in 40 CFR part 158, subpart B, involves the use of ''data tables'' to facilitate the identification of the applicability of the data requirements. In essence, the data requirements illustrate the questions the registrant will need to answer about the safety of the pesticide product before the Agency can register it. Because of the variety of chemicals and use patterns, and because EPA must retain flexibility to tailor data requirements as appropriate, only qualitative descriptors are in the tables. Test notes provide more specific information on the applicability of specific data requirements.

The table descriptors NR (not required), R (required), and CR (conditionally required) should be viewed as a general presentation, indicating the likelihood that the data requirement applies. The use of R does not necessarily indicate that a study is always required, but that it is more likely to be required than not. For example, if the applicant wanted to apply his pesticide to apples, then crop field trials would be required almost always on apples. However, if the physical/chemical properties of the chemical did not lend themselves to the test, such as performing an inhalation test with a chemical that is a solid and has an extremely low vapor pressure, then a waiver might be granted. Generally, test notes for R studies discuss any particular circumstances when the testing might not be required.

The use of CR means a study is less likely to be required. Triggers in the test notes indicate the circumstances under which the Agency has learned through experience that the information is needed. Although only an approximation, if percentages were to be assigned to indicate the need for a particular study, then R could be viewed as representing the submission of a study 50 to 100 percent of the time and CR would be up to 50 percent

Thus, NR, R, and CR are used for convenience to make the table format feasible, but serve only as a general indication of the applicability of a data requirement. In all cases, the test notes referred to in the table must be consulted to determine the actual need for the data.

The table format includes a column heading entitled ''Guideline,'' which refers to the OCSPP Harmonized Test Guidelines. Guideline numbers are provided as information/guidance to applicants. These Guidelines set forth recommended instructions and test methods for performing a study to generate the required data. Since these are guidance documents, the applicant is not required to use these Guidelines, but, may instead seek to fulfill the data requirement by other appropriate means, such as alternative test methods, submission of an article from open literature, or use of modeling. The applicant may submit a protocol of his own devising for the Agency to review. However, the OCSPP Harmonized Guidelines have been developed through a rigorous scientific process, including extensive peer review by the Advisory Panel (SAP). Additionally, many of the Guidelines have been harmonized internationally. As such, they represent the recommended approach to developing high-quality data that should satisfy EPA's data needs for risk assessment.

In addition, since it is not possible to sufficiently delineate all circumstances in test notes, consultation with EPA is encouraged. Applicants are also encouraged to visit the Agency's Web site at *http://www.epa.gov/pesticides/regulating/data_requirements.htm.*

C. Efforts to Incorporate 21st Century Science into Pesticide Decision Making

Over the next several years, EPA's Office of Pesticide Programs (OPP) is committed to improving and transforming the Agency's approach to pesticide risk management by enhancing the Agency's ability to use integrated approaches to testing and assessment. The Pesticide Program plans to maximize use of existing data from similar compounds, including information from new *in silico* and *in vitro* predictive models and exposure modeling to target *in vivo* toxicity testing that is needed to assess and manage chemical risks appropriately.

Over the next decade, as experience is gained and as the Agency's understanding of toxicity pathways increases, an enhanced integrated testing and assessment approach will be implemented for all pesticides. The approach will fully integrate hazard and

exposure information using advanced computer modeling of new *in vitro* data and an understanding of toxicity pathways to better predict risks and to determine what additional data are necessary to provide a sound basis to manage risks of concern. Data from improved biomarkers of exposure and biological outcomes from population-based studies will be used to evaluate the effectiveness of this new risk assessment paradigm, to readily identify early effects in exposed populations, and to improve the approach.

Current Agency scientific and regulatory practice provides the foundation for this final rule. While current practice is still largely dependent on animal (*in vivo*) testing, this rule is one milestone towards the Agency's longer term vision for 21st Century Toxicology and new integrated testing strategies. OPP believes that certain classes of chemicals, such as antimicrobial pesticides, provide an appropriate starting point for OPP's planned transformation. Many antimicrobials have both pesticidal and non-pesticidal uses. In addition, many antimicrobial products are regulated under multiple jurisdictions. Thus, many antimicrobial chemicals have been assessed by other regulatory programs and agencies. The ready availability of published literature and publicly-available assessments offer a unique opportunity for the applicant to use the available information as a starting point for fulfilling data requirements, and, when appropriate, to use computer modeling and/or *in vitro* data to supplement or fulfill data requirements. For example, OPP established a voluntary pilot program for eye irritation testing of certain antimicrobial pesticides using non-animal test methods. OPP will continue to evaluate use of new *in vitro* and computer-based approaches in OPP's hazard and risk assessment processes as the technologies are sufficiently developed and peer-reviewed. Certain tools are already available or anticipated to become available in the near term including, (Quantitative) Structure-Activity-Relationship (Q)SAR/expert systems and *in vitro* high through-put screening technologies. Furthermore, in conjunction with the International Life Sciences Institute (ILSI), OPP is currently pursuing the development of an application of the thresholds of toxicological concern (TTC) concept to evaluate antimicrobial pesticides. In collaboration with OPP, EPA's Office of Research and Development (ORD) is providing momentum for achieving the vision of 21st Century Toxicology by developing and evaluating new technologies in molecular, cellular, and computational sciences to supplement or replace more traditional methods of data development. OPP believes that its goal of using 21st Century science in integrated approaches to testing and assessment is achievable with strong scientific and stakeholder support through a transparent process. As the enhanced integrated testing and assessment approach matures, based on these scientific advances, EPA may determine to update its data requirements to reflect evolving program needs as specified in § 158.30(c). See Unit XVIII. of the proposed rule for further discussion of EPA's use of integrated approaches to testing and assessment.

III. Public Comments on the Notice of Proposed Rulemaking (NPRM)

A. Comments Submitted to EPA

This unit discusses, in general terms, the public comments received on the NPRM that appeared in the **Federal Register** of October 8, 2008 (73 FR 59382), and EPA's responses to those comments. The comment period for the NPRM was extended from January 6, 2009 to April 6, 2009, to allow stakeholders additional time to submit their comments. In addition, EPA convened a public workshop in Arlington, Virginia, to explain the provisions of the NPRM on November 6, 2008. The proposed rule, the notice of the extension of the comment period, the notice of the public meeting, the presentations used at the public meeting, the comments submitted, and EPA's Response to Comments Document are available in the docket for this rule.

During the public comment period, EPA received comments on the proposed part 158, subpart W regulations from 29 entities. There were also late comments received at meetings held at EPA in Arlington, VA on December 2, 2009, and June 14, 2010, as well as at a meeting on May 17, 2011, and in a letter dated June 17, 2011. The presentation materials and EPA's summary of the meetings, and the letter with attachments are included in the docket. These late comments were not new comments, but rather restatements of issues presented in their original comments submitted to EPA, and are also available in the docket. Another late comment, received on September 1, 2010, was addressed by adding additional comments and responses to the toxicology section of the Response to Comments Document.

EPA carefully reviewed all comments submitted, and provides responses in the Response to Comments Document, a copy of which is available in the docket. The Response to Comments Document also contains the rationale for the changes that were made from the proposed rule to the final rule, in response to submitted comments. Similar comments are grouped together. Comments that had a substantive impact on changes from the proposed rule to the final rule are also discussed in Units IV. to XXII. of this document.

B. Overview of This Final Rule

1. *In general.* This final rule reflects updates and revisions to the data requirements currently contained in 40 CFR part 161, in many cases by codifying the case-by-case data requirements decisions made over the years to help apply the agriculturally-based 1984 data requirements to antimicrobial pesticide products. The antimicrobial data requirements are being relocated to 40 CFR part 158, subpart W, and 40 CFR part 161 is being removed.

Based on comments received, EPA revised the proposed data tables. EPA's Response to Comments Document contains the rationale for the changes that were made from the proposed rule to the final rule in response to submitted comments.

Eleven new data requirements for antimicrobial pesticides are being codified in this final rule. As discussed in the preamble to the proposed rule, a ''new'' data requirement ''means that the data requirement has never been required or has rarely been required on a case-by-case basis, and has not been routinely considered during the Agency's evaluation of the data needed for the purpose of risk assessment'' (73 FR 59387). Eight new data requirements that were proposed in 2008 and are now being codified are: Developmental neurotoxicity; immunotoxicity; photodegradation in soil; soil residue dissipation; ready biodegradability study; porous pot study; activated sludge sorption isotherm study; and modified activated sludge, respiration inhibition test. The developmental neurotoxicity and immunotoxicity tests are new compared to part 161, but were added for conventional pesticides in the 2007 amendments to part 158. The photodegradation in soil study was not previously required for wood preservatives. The other four studies are unique to antimicrobials.

Based on comments received, two other ''new'' data requirements are being added that serve as alternatives to tests that were proposed (and are now being finalized): Simulation tests to assess the biodegradability of chemicals

in discharged wastewater, and simulation test—aerobic sewage treatment: Activated sludge units. Similarly, also based on comments, one ''new'' data requirement, the nature of the residue on surfaces, is being added as a more definitive trigger or screen for determining whether one of the studies that was proposed—the migration study—must be conducted.

Additionally, this final rule:

- Codifies data requirements/use pattern combinations that were not codified in part 161, but have typically been required to register an antimicrobial pesticide product.
- Provides improved definitions for antimicrobial pesticides used for public health and nonpublic health purposes.
- Codifies data requirements to determine risks to WWTPs and the potential for movement of antimicrobials and their degradates from the indoor environment to the outdoor environment via effluent discharge from a publically owned treatment work (POTW).

The data requirements promulgated in this final rule identify the types of information that EPA needs to determine whether an antimicrobial pesticide product should be registered and to make decisions regarding tolerances or tolerance exemptions for pesticide residues in food. Subpart W to part 158 includes a series of tables and regulatory text that mirrors the structure of the data requirements for conventional pesticides. However, subpart W establishes specific data requirements for each scientific discipline (except product chemistry) for antimicrobial pesticides. As explained in Unit II.A. of this document, subpart D to part 158, which contains the product chemistry data requirements for conventional pesticides, also applies to antimicrobials. The order of subpart W also mirrors that of the larger part 158. As such, the following data requirements categories are included in detail in part 158, subpart W: Product performance, hazard/toxicity (both human health and ecological toxicity), exposure (both application and post-application human exposures), residue chemistry, and environmental fate requirements.

EPA is also codifying 12 antimicrobial use patterns, as described in the proposed rule (73 FR 59389, October 8, 2008). As part of this final rule, EPA has developed an Antimicrobial Use Site Index to provide additional information about these use patterns. This index is included in the docket and is posted on the Agency's Web site.

2. *Changes from what was proposed.* In response to comments, EPA has made numerous changes to the proposed requirements in crafting the final rule. The most significant changes are summarized as follows.

i. *Alternatives to the porous pot study.* With regard to the porous pot study in the final environmental fate data requirements table in § 158.2280, EPA is adding two simulation studies that can serve as an alternative to the porous pot study. This change was based on a comment that requested consideration of whether ''studies that simulate wastewater treatment plants (WWTPs) [could] substitute for [the porous pot study].'' (ACC Comment identified in the docket by document ID number EPA–HQ–OPP–2008–0110–0088.9; Appendix H, entitled ''Comments on Proposed Data Requirements for Environmental Fate'' p. 5). Additionally, in the commenter's suggested environmental fate data requirements table (p. 11), instead of giving the title of the study as ''Porous Pot,'' the commenter wrote ''Simulated WWTP; e.g., Porous Pot Study.''

EPA agreed with the commenter and identified two other studies: The biodegradation in activated sludge study as described in the OPPTS guideline entitled ''Simulation Tests to Assess the Biodegradability of Chemicals Discharged in Wastewater'' and simulation test—aerobic sewage treatment: Activated sludge units. This change provides applicants with more flexibility in meeting this data requirement. EPA's rationale is described in Unit XV.A., and for greater detail see response to comment 134.1 in the Response to Comments Document in the docket. Test note 3 to the final environmental fate data requirements table in § 158.2280 clearly specifies that only one biodegradation study is to be submitted.

In creating a tiered structure for the antimicrobial environmental fate data requirements table, the table and accompanying test notes are intended to be used to determine which antimicrobials would be expected to reach a WWTP. Test notes 18, 19, 20, and 21 to the environmental fate data requirements table discuss specific criteria for determining whether data from a biodegradation study, the activated sludge sorption isotherm study, and the activated sludge respiration inhibition test are required for a particular product based on its intended uses.

ii. *Trigger for migration study.* EPA made changes to the trigger for the migration study in the final Residue Chemistry Data Requirements in § 158.2290. In its proposed rule, EPA ''triggered'' the migration study based on anticipated instances such as theoretical (modeled) estimates yielding a risk of concern. One commenter submitted a suggested residue chemistry data requirements table with a line-item entitled ''Nature of residue of surface.'' (ACC Comment, identified in the docket by document ID number EPA–HQ–OPP–2008–0110–0088.10; Appendix I, entitled ''Comments on Proposed Data Requirements for Residue Chemistry'' p. 7). A different commenter also submitted a different residue chemistry data requirements table, which also included the same line-item entitled ''Nature of residue on surface.'' (CSPA Comment, identified in the docket by document ID number EPA–HQ–OPP–2008–0110–0086.2).

The commenters' suggestion of requiring a nature of the residue study on surfaces provides a more definitive trigger for the migration study. EPA is adding a nature of the residue on surfaces study. As specified in test note 5 to the final Residue Chemistry Data Requirements Table, the results of the nature of the residue on surfaces study will serve as a trigger for determining whether the migration study will need to be performed. EPA considers the commenters' suggestions to be a valuable addition to the final residue chemistry data requirements table in § 158.2290 that provides more definitive triggers to help define and narrow the instances of higher-tiered testing.

iii. *Changes to data requirements for wood preservatives.* As discussed in Unit VI.B., EPA's current practice of determining the data required for a wood preservative product is dependent upon where the product is intended to be used (land-only versus land and aquatic). This approach also assumes that diversion does not occur and that wood that is treated for land-only uses does not end up in the water and vice versa. In practice, it is difficult to assure that diversion does not occur. Accordingly, in response to comments, the Agency determined that all treated wood needs to be considered as having the potential to come into contact with surface water. Therefore, for the final Environmental Fate Table, for the wood preservatives column, the data requirements for anaerobic soil metabolism, aerobic aquatic metabolism, and anaerobic aquatic metabolism were changed from ''CR'' to ''R.'' For the final Nontarget Organism Table, for the wood preservatives column, the data requirements for chronic toxicity testing with fish (fish early-life stage) and aquatic invertebrate (aquatic invertebrate life-cycle) are

being changed from ''CR'' to ''R'' to provide chronic data when chronic exposure is expected. With regards to the three acute toxicity tests conducted with the TEP, the ''NR'' in the wood preservatives column is changed to ''CR.'' Additionally, EPA will perform a down-the-drain analysis for every product with an applicable use or exposure scenario, including wood preservatives, that has the potential for waters containing antimicrobials to reach a WWTP. Therefore, to perform this analysis, the Agency is requiring data on the biodegradation of a wood preservative and its potential toxicity to WWTP microorganisms in an activated sludge basin.

iv. *Changes to data requirements for antifoulants.* Antifoulants are released/applied directly to the aquatic environment. These products are often manufactured to be persistent, and because of the continuous release process, some of the active ingredient is likely to be transferred to the bottom of the water column, and then be adsorbed to the sediment. Therefore, EPA is changing, in the final Environmental Fate Data Requirements Table, the ''CR'' for the aquatic sediment study for the antifoulant paint and coatings column to ''R.'' With regards to the three acute toxicity tests conducted with the TEP, the ''NR'' in the antifoulant paint and coatings column is changed to ''CR.'' Also, to perform a down-the-drain analysis, the Agency is requiring data on the biodegradation of an antifoulant and its potential toxicity to WWTP microorganisms in an activated sludge basin.

v. *Non-dietary ingestion.* EPA proposed to require this post-application exposure study. However, EPA agrees that instead of requiring this study, it is more likely that EPA would model this route and pathway of exposure using inputs from available and reliable published research. Therefore, EPA has removed this data requirement from the final Post-Application Exposure Table.

vi. *Re-structuring of proposed toxicology and residue chemistry data requirement tables.* In the proposed rule, for the toxicology data requirements table, EPA separated those use patterns needing more toxicology data from those needing less toxicology data using a terminology described as high or low. Based on comments received, in this final rule, EPA is now using a food/nonfood approach with some similarities to that of the toxicology data requirements table for conventional pesticides to distinguish the use patterns that need more toxicity data from those that need less. The food-use column and the nonfood-use column are split into subcolumns to explain which food-uses or nonfood-uses require more data, and which require less. This modification of the food/nonfood approach delineates the specific data requirement needs for antimicrobial pesticides.

For the final residue chemistry data requirements table, EPA has adopted the commenters' suggestion for a tiered format. After review of the commenter's suggested tables, EPA believes the commenters' suggested tiered approach is more suitable to antimicrobials than that proposed by EPA.

vii. *Change in terminology.* The commenters' asserted that the use of terms such as ''high'' or ''low'' as a means of tiering was insupportable, and an ''unsubstantiated assignment of exposure categories'' (ACC Comment, identified in the docket by document ID number EPA–HQ–OPP–2008–0110–0088.1, p. 21 and 22). EPA continues to believe that the use of ''high'' and ''low'' categories of exposure defined by the antimicrobial use patterns are a valid method for identifying those exposures that have greater exposure and those that have less. Based on its experience, EPA understands which use patterns require more data. However, EPA can achieve the same result without the use of the terms ''high'' or ''low.'' Therefore, based on comments received, EPA notes that it is no longer using the terms ''high human exposure'' and ''low human exposure'' as table headers for the final Antimicrobial Toxicology Data Requirements Table. Similarly, EPA is no longer using the terms ''high environmental exposure'' and ''low environmental exposure'' as table headers for the final Antimicrobial Nontarget Organism, the Nontarget Plant Protection, or the Environmental Fate Data Requirements Tables. However, EPA also notes that terms such as ''high human exposure,'' ''low human exposure,'' ''high environmental exposure,'' and ''low environmental exposure,'' can be appropriate when discussing a particular antimicrobial use. A statement that a particular use results in, for example, ''high environmental exposure'' provides information and alerts the reader that more data are likely to be needed, rather than less data.

IV. Scope of the Rule

This rule establishes a separate listing in Title 40 of the CFR for EPA's data requirements under FIFRA and FFDCA section 408 for antimicrobial pesticide uses. Although the rule is tailored to the unique characteristics of antimicrobial pesticides, it builds upon the existing data requirements imposed in 1984 on all pesticides and the 2007 amendments to those requirements pertaining to conventional pesticides. Both sets of data requirements—conventional and antimicrobial—are designed to provide EPA with the information needed to make the required regulatory determinations under FIFRA and FFDCA section 408. FIFRA provides that a pesticide may not be registered for sale, distribution, and use unless ''it will perform its intended function without unreasonable adverse effects on the environment. . . .'' [7 U.S.C. 136a(c)(5)(C)]. FIFRA defines ''unreasonable adverse effects on the environment'' as both ''any unreasonable risk to man or the environment'' and ''a human dietary risk . . . inconsistent with the standard under section 408 of the [FFDCA]'' [7 U.S.C. 136(bb)]. FFDCA section 408 directs that EPA shall not establish a tolerance permitting pesticide residues in food unless EPA determines that the tolerance is ''safe'' [21 U.S.C. 346a(b)(2)(A)(i)]. ''Safe,'' under FFDCA section 408, is defined as ''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'' [21 U.S.C. 346a(b)(2)(A)(ii)]. In making safety determinations, EPA is required to consider aggregate and cumulative exposures from pesticides and other related substances and multiple factors specifically related to the protection of children [21 U.S.C. 346a(b)(2)(C) and (D)].

Under FIFRA, EPA has required ''[s]ubstantial amounts of data on the pesticide, its composition, toxicity, potential human exposure, environmental properties, and ecological effects, as well as information on its product performance (efficacy) in certain cases'' (73 FR 59384, October 8, 2008). Since 1984, EPA has had codified FIFRA data requirements mandating data on, among other things, the toxicity hazards from ingestion of pesticides and exposure levels of pesticide residues in food (Ref. 2). With the passage in 1996 of the Food Quality Protection Act, [Pub. L. 104–170, 110 Stat. 1489 (1996)], which added the expanded safety standard in FFDCA section 408 described previously, EPA's data needs have expanded. As noted in the preamble to the proposed rule, ''[t]he combination of aggregate and cumulative exposure assessments required by FFDCA section 408 increases the nature and scope of EPA's

risk assessment, and potentially increases the types and amounts of data needed to determine that the FFDCA safety standard is met'' (73 FR 59385, October 8, 2008). Moreover, with the explicit linkage in FIFRA between the FIFRA and FFDCA section 408 safety standards (also added by FQPA), ''[t]he data required to support a determination of 'reasonable certainty of no harm' under FFDCA are an integral part of the data needed for an 'unreasonable adverse effects' determination under FIFRA'' [Id.; *see* 72 FR 60934, October 26, 2007 (FRL–8106–5), recodifying part 158 data requirements under the authority of both FIFRA and FFDCA section 408]. This rule, establishing specific data requirements for antimicrobial pesticides, is designed to capture the broad range of data needed to assess the safety of pesticides under the standards of both FIFRA and FFDCA section 408.

The ACC Biocides Panel and other commenters, however, have claimed that the scope of the proposed rule exceeds the EPA's statutory authority because EPA is asserting ''jurisdiction under FIFRA over some antimicrobial food uses where, in the Panel's view, the statutory scheme provides exclusive jurisdiction to FDA'' (Food and Drug Administration). (ACC Comment identified in the docket by document ID number EPA–HQ–OPP–2008–0110–0088.1, p. 31). Although the ACC Biocides Panel acknowledges that these uses are properly regulated by EPA as ''pesticides'' under FIFRA, the Panel argues that ''EPA's responsibility for such use[s] is to evaluate whether the antimicrobial meets the standard for registration under FIFRA, taking into account FDA's existing regulatory finding [under FFDCA section 409]. . . . EPA does not have the authority under either FIFRA or FFDCA to review or change the terms of the FDA approval.'' (ACC Comment, identified in the docket by document ID number EPA–HQ–OPP–2008–0110–0088.1, p.33). In essence, the Panel is asserting that for these antimicrobial uses, EPA is without authority or jurisdiction under FIFRA to evaluate, or require data on, the level of risk from dietary exposure to the antimicrobial—where FDA has evaluated the safety of the use of the substance under section 409. As a basis for this argument, the ACC Biocides Panel points to the Antimicrobial Regulation Technical Corrections Act (ARTCA), [Pub. L. 105–324, in 1998], which divided FFDCA jurisdiction between EPA and FDA with respect to antimicrobials. The Panel further argues that EPA is wrong to rely on FIFRA section 2(bb)'s inclusion of the FFDCA section 408 safety standard in the definition of ''unreasonable adverse effects'' as authority for requiring data on antimicrobial uses falling under FDA's FFDCA section 409 jurisdiction. Labeling EPA's interpretation of FIFRA section 2(bb) in the proposed rule as ''new,'' the ACC Biocides Panel claims that EPA has contradicted its ''long-standing'' interpretation of this provision.

The ACC Biocides Panel fundamentally misunderstands EPA's statutory authority under FIFRA to require data pertaining to dietary risk from pesticides. EPA's authority to regulate pesticides under FIFRA with regard to their dietary risk is derived from FIFRA not the FFDCA. Under FIFRA, EPA is charged with protecting the public from ''unreasonable adverse effects on the environment.'' As noted previously, FIFRA in section 2(bb) defines ''unreasonable adverse effects'' in the first instance as ''any unreasonable risk to man. . . .'' [7 U.S.C. 346(bb)]. This broad standard clearly encompasses any unreasonable dietary risk. EPA's authority to regulate pesticides under FIFRA on the basis of dietary risk is explicitly reinforced by the second part of the unreasonable adverse effects standard which directs EPA to evaluate ''human dietary risks'' from ''pesticides'' under the safety standard in FFDCA section 408. [Id.]

Nothing in FIFRA or the FFDCA limits or constrains EPA's authority or jurisdiction to regulate pesticides based on dietary risk under FIFRA section 2(bb). The FIFRA section 2(bb) standard is independent from the safety standard under FFDCA section 409. Further, any finding by EPA under FIFRA that considers dietary risk would not ''change the terms of a FDA approval;'' rather, it would simply be a determination as to whether the separate FIFRA regulatory standard had been met. Finally, contrary to the ACC Biocides Panel's contention, the adjustment by the ARTCA of EPA's and FDA's jurisdiction under FFDCA sections 408 and 409 over antimicrobials does not affect EPA's jurisdiction or authority with regard to dietary risks of pesticides under FIFRA. In fact, as explained further in this unit, not only did the ARTCA not amend FIFRA section 2(bb) but Congress in the ARTCA took the unusual step of expressly disavowing any intent to narrow the scope of EPA's authority under FIFRA.

The ARTCA was follow-on legislation to the major 1996 FFDCA amendments which, among other things, changed EPA and FDA jurisdiction under FFDCA sections 408 and 409. Prior to 1996, section 408 of the FFDCA, which is administered by EPA, only applied to ''pesticide chemicals'' that were defined as FIFRA ''pesticides'' ''used in the production, storage, and transportation of raw agricultural commodities'' [21 U.S.C. 321(q) (1994)]. FIFRA pesticide residues in food not falling within this provision (i.e., FIFRA pesticides used later in the food production process than the growth of raw agricultural commodities) came under section 409 of the FFDCA as food additives [*See* 21 U.S.C. 321(s), 348 (1994)]. FDA administers the establishment of food additive regulations under FFDCA section 409. Many antimicrobial pesticides used in conjunction with the manufacturing and processing of foods, at that time, were regulated as food additives. This division of legislative authority was changed by the FQPA in 1996. The FQPA amended the definition of ''pesticide chemical'' in the FFDCA to make it co-terminous with the definition of a ''pesticide'' in FIFRA by deleting the language restricting pesticide chemicals to those pesticides used in the production of raw agricultural commodities. Correspondingly, the FQPA also excluded ''pesticide chemicals'' from the definition of a ''food additive'' [Pub. L. 104–170 sec. 402, 110 Stat. 1489, 1513 (1996)]. This change had the effect for FFDCA purposes of bringing all FIFRA pesticides under FFDCA section 408. Not only did Congress consolidate regulation of all pesticide residues in FFDCA section 408 but it also amended FIFRA to insure that the new safety standard in FFDCA section 408 was part and parcel of the FIFRA registration standard for pesticides resulting in residues in food [7 U.S.C. 136(bb)(2)]. Specifically, in section 2(bb)(2), Congress defined an ''unreasonable adverse effect on the environment'' under FIFRA as ''a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under FFDCA section 408 [21 U.S.C. 346a].''

In 1998 in the ARTCA, Congress modified slightly its FFDCA decision to consolidate all pesticide chemical residues in foods under FFDCA section 408. ARTCA amended the definition of ''pesticide chemical'' in FFDCA section 201 to exclude certain antimicrobial substances from the coverage of the definition [*See* 21 U.S.C. 321(q)]. More specifically, with certain qualifications, the ARTCA excepted, from the definition of pesticide chemical, substances that are FIFRA pesticides and are ''applied for [an antimicrobial]

use on food, or the substance is included for such use in water that comes into contact with food, in the preparing, packing, or holding of the food for commercial purposes.'' [21 U.S.C. 321(q)(1)(B)(i)]. In addition, ARTCA excepted substances from the definition of pesticide chemical that are food contact substances, as defined in section 409(h)(6) of the FFDCA, based on certain circumstances related to their use. These antimicrobial substances were now no longer considered ''pesticide chemicals'' under the FFDCA but fell under the definition of ''food additive.'' That had the effect of shifting the residues resulting from these antimicrobial substances from FFDCA section 408 to FFDCA section 409 and shifting agency jurisdiction under the FFDCA over the same from EPA to FDA. Importantly, Congress, in ARTCA, did not amend FIFRA to remove these uses of antimicrobial substances from the definition of ''pesticide'' under FIFRA and left unchanged FIFRA section 2(bb)(2) which mandates that the section 408 safety standard is part of FIFRA's unreasonable adverse effects standard as to FIFRA ''pesticide'' residues on food. Thus, EPA retained FIFRA jurisdiction over these antimicrobial substances (because they remained FIFRA ''pesticides'') while FDA reacquired FFDCA jurisdiction over them under FFDCA section 409 (because they were removed from the definition of ''pesticide chemical''). To make clear its intent on EPA's FIFRA jurisdiction, the ARTCA included the following express disavowal which was inserted into the FFDCA definition of ''pesticide chemical'':

> With respect to the definition of the term 'pesticide' that is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act, this clause [excluding certain antimicrobial substances from the FFDCA definition of ''pesticide chemical''] does not exclude any substance from such definition'' [21 U.S.C. 321(q)(1)(B)].

Since its passage, EPA has interpreted the ARTCA according to its plain language, excluding the designated antimicrobial substances from the coverage of FFDCA section 408 but continuing to regulate those antimicrobial substances that qualify as FIFRA ''pesticides'' under FIFRA and requiring that, when those antimicrobial pesticides result in residues in food, the risks from such residues be consistent with the safety standard in FFDCA section 408. After all, FIFRA section 2(bb)(2), on its face, applies to FIFRA ''pesticides'' and not FFDCA ''pesticide chemicals.'' Any other result would be directly contrary to Congress' dictate that it was not excluding any substances from the FIFRA definition of ''pesticide.'' Accordingly, it is well within EPA's FIFRA authority to require that data be submitted on pesticides to determine if those pesticides meet the FFDCA section 408 safety standard, whether or not those pesticides come within the definition of a FFDCA ''pesticide chemical,'' so long as the use of those pesticides results in residues in food. On the other hand, the ACC Biocides Panel's approach would involve amending the language of section 2(bb)(2) in a manner specifically rejected by the Congress when it passed ARTCA.

There is no basis for the ACC Biocide Panel's claim that EPA's interpretation of FIFRA section 2(bb)(2) is ''new.'' The best evidence of the consistent and long-held nature of EPA's interpretation are the numerous submissions to the Agency from the Panel (and others) over the last 10 years disputing EPA's plain language approach to FIFRA section 2(bb)(2). (Refs. 3, 4, 5, 6, 7, 8, 9, 10 and 11)

V. Issues Repeated Throughout Most Comments

In evaluating the comments received on proposed part 158, subpart W, EPA noted that four specific comments were routinely repeated throughout most of the entire set of comments. Additional discussion can be found in the Response to Comments Document available in the docket to this rule.

A. Differentiating the Review of Antimicrobials

1. *Comment.* EPA received several comments noting that FIFRA section 3(h)(3)(A)(ii) specifies that EPA must differentiate the review of antimicrobial pesticides from that of other pesticides.

2. *EPA's response.* FIFRA section 3(h)(3)(A)(ii) specifies, among other things, that, in proposed regulations to accelerate and improve the review of antimicrobial pesticide products, EPA shall define the various classes of antimicrobial use patterns, differentiate the types of review undertaken for antimicrobial pesticides, conform the degree and type of review to the risks and benefits presented by antimicrobial pesticides, and ensure that the registration process is sufficient to maintain antimicrobial product efficacy. While those elements apply to a proposed rulemaking that the Agency published on September 17, 1999 (64 FR 50671) (FRL–5770–6), the Agency has been mindful of those same elements in its development of part 158, subpart W. As applied to antimicrobial product registration actions, differentiation refers to the tailoring of data requirements so that they are responsive to considerations about the antimicrobial products to which they relate. In practice, differentiation means that the data requirements applied to antimicrobials are designed to respond to the special or unique needs of antimicrobials such as the nature of the products, their ingredients, their uses, etc. Differentiation or tailoring does not mean that the resulting data requirements for antimicrobials will necessarily be comprised of more, less, or the same number and type of data requirements as required for other types of pesticides such as conventional pesticides.

For example, the residue chemistry data requirements for conventional pesticides focus on the application of agricultural pesticides to crops growing in the fields. However, the residue chemistry data requirements for antimicrobials, codified in this final rule, have been tiered to account for applications that focus not on crops growing in the fields (where antimicrobials are rarely used), but instead account for antimicrobial uses, including those that result in residues on food more indirectly, such as from use as sanitizers in food processing plants. The overall impact is to require fewer studies since the tiering used for the antimicrobial residue chemistry data requirements table is structured differently, and there are fewer ''R'' studies and most studies are ''CR.'' However, there are two residue chemistry data requirements (migration and nature of the residue on surfaces) for antimicrobials that are not included in the conventional residue chemistry data requirements table because they reflect the unique use sites for antimicrobials; see Unit XVI. for additional discussion. Ecotoxicity and environmental fate data requirements provide another example of the differentiation of data requirements between antimicrobials and conventional pesticides. While conventional or biochemical/microbial pesticides are often used outdoors, and are deliberately placed/spread in the environment, most antimicrobials are used indoors. As discussed in the preamble (73 FR 59406), previously EPA had assumed that many of the indoor uses went down the drain to a WWTP, where the WWTP processes would mitigate environmental concerns. Therefore, in 1984, EPA required basic ecotoxicity and environmental fate data for conventional pesticides but made these types of data conditional for indoor uses such as antimicrobials based on whether antimicrobial-specific

data indicated that environmental exposure may occur. However, as discussed in the proposed rule (73 FR 59407), in recent years there have been detections of antimicrobial chemicals (with indoor uses) in waterbodies. These antimicrobials are moving into the environment via treated effluent. Therefore, EPA is requiring for antimicrobials a specific tiered-set of data to evaluate the likelihood of environmental exposure to antimicrobials that may reach a WWTP, as a result of being washed down the drain via leachates, rinsates, and flushes. These data evaluate whether antimicrobials are likely to survive the treatment processes at a typical WWTP, and thus would be present in the WWTP effluent. Antimicrobials that do survive the treatment processes have the potential to end up in the terrestrial or aquatic environments and higher-tiered ecotoxicity and environmental fate data are only triggered for these antimicrobials.

Thus, differences in data requirements stem directly from the inherent differences in the nature of the particular type of pesticide used. Even with such differentiation or tailoring, there is a general core of data requirements which may be expected to be applicable to any kind of pesticide product, such as product chemistry data requirements. EPA's ultimate goal with its antimicrobial data requirements is to create a body of data requirements which produce sufficient information for the Agency to consider and use in making its statutorily-required determinations regarding the risks and benefits, where applicable, of antimicrobial pesticides. The differentiation or tailoring of the antimicrobial data requirements is instrumental in accomplishing that goal.

B. Rewrite and Repropose the Rule

Several commenters requested that EPA rewrite and then repropose this rule. Commenters raised three arguments as to why EPA should repropose. First, the proposed regulation does not contain scientifically-based criteria for determining data requirements but instead requires that data requirements be determined in case-by-case consultations in which EPA retains ''sole discretion'' as to the data required. Second, EPA has not disclosed how it plans to use the proposed data in EPA risk assessments. Third, affected parties cannot properly evaluate the data requirements without final guidelines on how such studies should be conducted. Each of these three arguments are addressed in detail in the following responses.

1. *Comment on scientifically-based criteria.* Several commenters focused on the test notes to the data requirements tables, and claimed that the proposed rule ''leaves too many standards and decisions to the sole discretion of EPA, creating uncertainty and, inevitability, inconsistency in regulatory decision making.'' Too many determinations, the commenter asserted, are at ''EPA's discretion'' because the proposal is vague, without clear-cut criteria. Additionally, they argued that there are too many places in the test notes where consultation with the Agency is required or the phrase ''as determined by the Agency'' is used. (One commenter listed 37 instances in which the proposal allegedly substituted a mandatory consultation process for regulatory criteria.) According to the commenters, EPA should eliminate most of the consultation requirements and instead, repropose the rule providing a clear set of requirements.

2. *EPA's response to comment on scientifically-based criteria.* Test notes often contain qualitative or quantitative measures for use in determining whether a study is triggered or not. Most frequently this occurs when there is an initial study that relates to whether subsequent testing would be needed or not. Not all triggers are easily reduceable to quantitative measures and EPA believes that qualitative descriptors such as ''expected to enter the environment in significant concentrations,'' or ''if repeated dermal exposure is likely to occur under conditions of use,'' and ''the use of the pesticide is likely to result in repeated human exposure over a considerable portion of the human lifespan'' provide meaningful criteria for determining when a study is triggered. EPA has carefully reviewed each of the 37 test notes cited by one commenter and has identified several instances in which clarification of the criteria was appropriate. EPA's analysis of these 37 test notes and resultant changes are included in response to comment 3 in the Response to Comments Document in the docket.

In numerous places the test notes contain language stating that the criteria would be applied ''as determined by the Agency.'' Commenters have misinterpreted this as giving EPA the authority to make decisions on factors other than the regulatory criteria included or in its ''sole discretion.'' This was not EPA's intent and, accordingly, EPA has removed all of the phrases ''as determined by the Agency'' from all test notes for the final antimicrobials rule so there can be no chance of a misunderstanding of how the criteria are to be applied.

Commenters also asserted that the EPA's alleged mandatory consultation requirements rendered the test notes meaningless, as EPA would determine whether studies were required in private based on unspecified factors. EPA disagrees. The commenters have misread the proposed rule language and misunderstood the purpose for consultation. The consultation references were not intended to impose a mandatory consultation requirement. To the contrary, references to consultation were an attempt by EPA to signal its willingness to meet with applicants to adapt studies, if necessary, to the specifics of individual antimicrobials.

Consultation is a longstanding, commonly used and valuable process in EPA's Pesticide Program. Applicants often meet with OPP staff on a pre-submission basis to review and discuss the adequacy of the available data. OPP believes that such meetings are beneficial to both EPA and the applicants. In practice, such meetings are very often sought by registrants and applicants. By encouraging communication and exchange of ideas, such discussions can help in the development of clearer expectations of what must be submitted in instances where data requirements involve complexities. Consultation can result in data that better meets EPA's needs and saves resources for both EPA and the applicant. Depending upon what is intended to be addressed, such meetings do not necessarily need to be held in person, but can be frequently accomplished via teleconferencing.

EPA did not intend its references to consultations in the test notes to impose mandatory consultation requirements; neither did EPA intend the consultation references as a means of establishing a different standard for determining if a study is triggered. EPA has carefully reviewed all test notes in the antimicrobials final rule and removed all references to consultation from all test notes for the antimicrobials rule so there can be no chance of misunderstanding the voluntary nature of consultation.

3. *Comment on use of data in risk assessment.* The commenters also argued that reproposal was necessary because they could not meaningfully comment on the proposal without understanding how the data would be used by EPA. Specifically, one commenter wrote: ''It is not plausible for [the commenter] or others to meaningfully comment on the Proposal

without the benefit of understanding the risk assessment approaches EPA plans to use, (e.g., human and ecological), the ways in which the data requirements will provide information to conduct those assessments and the ways EPA will use those risk assessments in making regulatory decisions.''

4. *EPA's response on use of data in risk assessment.* EPA disagrees with this comment for several reasons. First, how EPA conducts risk assessments and how it uses toxicological, ecological, and exposure data in those risk assessments is well known. Risk assessment is not unique to OPP. The principles used by OPP and, in fact, by EPA are those used by the scientific community in general. OPP follows the processes and procedures in the many risk assessment guidance documents that have been issued by EPA (see *http://www.epa.gov/riskassessment/guidance.htm*). The Agency's exposure and risk assessment procedures have been presented in numerous exposure and risk assessments for antimicrobial pesticides. EPA's assessments reflect the best available data, and the state of the science of exposure and risk assessment models, methods, and procedures.

Moreover, OPP's risk assessment procedures for pesticides are well-documented. EPA has concluded the process of completing Reregistration Eligibility Decision Documents for all pesticides under FIFRA and reassessing all FFDCA pesticide tolerances. This was a very open process involving multiple public comment opportunities as to each pesticide. Further, all regulatory decision documents as well as the underlying risk assessments have been made available to the public. EPA has now begun new pesticide reviews under the Registration Review program, and that process is equally open and transparent.

A second reason why EPA believes this comment to be misdirected is that the proposed rule does not represent a change to EPA's existing and transparent risk assessment procedures. Rather, the proposal is merely designed to tailor the existing data requirements that apply to all pesticides in a way that is more specific to antimicrobial pesticides, as well as including some new requirements applicable to antimicrobials.

Finally, the comment is without foundation because EPA has explained the need for each study and provided background information on the purpose for which each study would be required. Part 158, subpart B contains an extensive description of the need for and use of submitted studies (40 CFR 158.130). Additionally, as explained in the preamble to the antimicrobials proposed rule, EPA relied on the proposed and final rules for establishing data requirements for conventional pesticides. As stated in the proposed rule for antimicrobials, the rationales for requiring and/or revising particular data requirements were in those rules.

> With few exceptions, these rationales are also applicable to antimicrobial pesticide chemicals, and as such have not been repeated in today's proposed rule. Today's proposal discusses in detail only those revisions that are singularly applicable to antimicrobial pesticides, including antifoulants and wood preservatives.'' (73 FR 59384).

Examples of studies applicable to antimicrobial pesticides and for which a description of the need for the requirement was included in the preamble to the proposed rule for antimicrobials include the need for:

- The 90-day dermal and 90-day inhalation studies for heating, ventilation, air conditioning, and refrigeration uses (73 FR 59395),
- A food migration study (73 FR 59404), and
- Environmental fate studies to support a down-the-drain assessment (73 FR 59408).

One commenter presented several examples of what the commenter labeled as EPA's ''ad hoc risk assessment processes.'' An examination of those examples shows that the commenter is concerned with what it labels as ''inconsistency in EPA's current practice'' as to when a dietary risk assessment is needed for antimicrobial pesticides. The commenter argued that this alleged inconsistent practice shows the ''need for stable, transparent guidance on risk assessment to support data requirements regulation.'' EPA does not believe that it has been inconsistent in its risk assessments. Furthermore, EPA does not believe that such ''inconsistencies,'' if they exist, would mean that affected parties could not comment meaningfully on the proposed data requirements. Ultimately, the issue with the data requirements rule is whether EPA has asked for data needed for determining whether pesticides meet the relevant statutory safety standards. The fact that EPA might have been inconsistent in the past in its determinations with regard to the safety standard or how it went about assessing whether a pesticide met the safety standards (e.g., did EPA need to do a dietary risk assessment), does not handicap an affected party in determining whether a proposed data requirement is consistent with the statutory safety standards. To reiterate, the relevant question is not whether EPA has guidance on when dietary risk assessment is needed but whether the proposed data requirements pertaining to dietary risk would require information that are appropriate to EPA's determination under the applicable statutory safety standards. To the extent, the commenter is concerned with any particular Agency decision regarding when a dietary risk assessment is needed for antimicrobials, EPA encourages the commenter to raise that concern directly with the Agency in the context of the specific matter causing the commenter concern.

This commenter later filed additional comments that further developed the argument that reproposal is necessary because EPA allegedly has not clearly defined when a dietary risk assessment is needed. The commenter wrote: ''[T]he Proposal does not clearly articulate any standards for determining what uses trigger a food analysis. It has become apparent since the Proposal was issued that the Agency will interpret this regulation to vastly increase the number of antimicrobials regulated as food use.'' (ACC/CSPA letter, identified in the docket by document ID number EPA–HQ–OPP–2008–0110–0107, p. 2). Further, the commenter then asserts that ''EPA's economic analysis does not even attempt to address the increase in the burden on registrants and applicants that this [alleged] expansion of the need for 'food contact' approvals will cause.'' (Id.) These additional comments suggest that this commenter is concerned with EPA decisions issued prior to this final rule (and, in most cases, prior to issuance of the proposed rule) and fears how the final rule may be interpreted in the future. However, it is difficult to determine from these comments whether the commenter is claiming that this alleged ''expansion'' of food use antimicrobials is effected by any particular language in the proposed rule. To the extent the commenter is arguing that the expansion is caused by EPA's application of the FFDCA section 408 standard to all antimicrobial food uses under FIFRA section 2(bb) (whether the use requires clearance under FFDCA section 408 or 409), the commenter, as explained in Unit XVI.A., misunderstands EPA's authority under FIFRA and EPA's practice as to antimicrobials since the passage of ARTCA. In another place in its subsequent comments, the commenter argues that the use of the categories of ''direct food use'' and ''indirect food use'' ''creates the potential for almost all antimicrobials to be considered as possibly leaving residues on food.''

(ACC attachment 1, identified in the docket by document ID number EPA–HQ–OPP.2008–0110–0108, p. 4). However, EPA adopted the categories of direct and indirect food use as a way to tier data requirements for residue chemistry and toxicology, not to expand the category of food uses. For a use to qualify as an indirect food use it must result in residues in food and EPA clearly has the authority under FIFRA and the FFDCA to request data on and assess the risk of pesticide residues in food. Despite the commenter's claims to the contrary, it is not EPA's intent to use this data requirements rule as a basis for expanding what antimicrobial uses qualify as direct or indirect food uses. Accordingly, EPA's economic analysis has accurately captured the costs imposed by this rule.

5. *Comment on lack of final guidelines.* Finally, commenters argued that reproposal was needed because affected parties cannot properly evaluate the data requirements without final guidelines on how such studies should be conducted.

6. *EPA's response on lack of final guidelines.* EPA disagrees with this comment: EPA can require submission of a particular study even if no guideline has been provided. The types of data needed for EPA to make a registration decision are clearly identified in its proposed rule. Testing laboratories routinely conduct these studies, as evidenced by the test cost data which was available for use in both EPA's and the commenter's economic analyses. Final guidelines are available for the majority of tests required, and draft guidelines provide information for the applicant to consider. Since there was an understanding of the types of data EPA proposed to require, the commenter had sufficient information to comment on whether EPA had asked for the data needed for determining whether pesticides meet the relevant statutory safety standards.

It is important to keep in mind that, as noted in the proposed rule, new part 158, subpart W is ''retaining most current data requirements for antimicrobials . . . and revises other existing data requirements.'' (73 FR 59383) The guidelines that the commenter asserts as not providing sufficient information to permit meaningful comment pertain, for the most part, to these existing data requirements that are not being modified by this rulemaking. As to the ''new'' data requirements that are imposed by this rule, the commenter has not specifically explained why interested parties cannot meaningfully comment on these requirements or why a final guideline is needed to provide meaningful comments on these studies. In fact, as to these ''new'' studies, OCSPP guidelines (formerly OPPTS) are available for all except the nature of the residue on surfaces study. For that study, due to the many site- and chemical-specific variations, a protocol review is required.

This commenter later filed additional comments stating that ''FIFRA requires EPA to issue test guidelines.'' (ACC/CSPA letter, identified in the docket by document ID number EPA–HQ–OPP–2008–0110–0107, p. 4). In accordance with FIFRA section 3(c)(2)(A), EPA has promulgated data requirement rules ''specifying the kinds of information which will be required to support the registration of a pesticide.'' EPA is not required to issue guidance explaining how studies that are addressing the data required under the regulations should be performed. Additional information on EPA's development of guidelines is in Unit XVIII.

C. Alternative Testing Paradigms

1. *Comment.* A commenter asked how OPP plans to implement the National Academy of Sciences (NAS)/EPA Vision of Toxicity Testing in the 21st Century or the Strategic Plan for Evaluating the Toxicity of Chemicals. The commenter noted that the rule should be specific in identifying alternative approaches that EPA will consider.

2. *EPA's response.* In the proposed rule, in Unit XVIII., entitled ''Alternative Testing Paradigms,'' EPA discussed its commitment to moving towards a more efficient and refined testing/risk assessment paradigm for antimicrobial pesticide chemicals. That discussion included the following:

- OPP's current thinking on how Structure-Activity-Relationships (SAR) and Quantitative SAR (QSAR or (Q)SAR) modeling could be used as part of an integrated approach to hazard and risk assessment to support a regulatory decision-making process for antimicrobial pesticides.
- The evolution of the current paradigm of animal (*in vivo*) toxicity testing toward a more integrated tiered testing approach for antimicrobial pesticides.
- Development of computational tools for interpreting data from computational chemistry, high-throughput screening (HTS) and genomic technologies.
- The EPA-funded reports by the NAS entitled ''Toxicity Testing for Assessment of Environmental Agents'' (2006) and ''Toxicity Testing in the 21st Century: A Vision and a Strategy'' (2007).

The NAS recommendations are truly visionary and involve a transformative paradigm shift in toxicology based largely on the increased use of *in vitro* molecular and cellular assays, and computational modeling that make testing faster and less costly, and reduces animal testing significantly. The new technologies are expected to help EPA better understand how chemicals perturb normal biological function(s), and thus identify toxicity pathways. Potential toxic effects of chemicals could then be predicted based on *in vitro* bioactivity profiles derived from a chemical's effects on cellular molecules and processes. Thus, the scientific foundation for this new paradigm is based on linking *in vitro* effects with adverse outcomes *in vivo,* and on computer modeling that extrapolates to predicted responses in whole tissues, organisms and populations based on realistic human or environmental exposures.

EPA is working to develop and evaluate new technologies in molecular, cellular, and computational sciences to supplement or replace the more traditional methods of toxicity testing and risk assessment (see *http://www.epa.gov/pesticides/science/testing-assessment.html*). Such an approach begins with consideration of exposure information along with hazard-based hypotheses about the plausible toxicological potential of a chemical or group of chemicals based on their physical-chemical properties and their effects on biological targets *in vitro.* This information is then combined with computer modeling to target animal testing to the specific data needed for human health and ecological risk assessments.

No single new technology will be able to address all situations. However, by using a suite of tools and approaches in combination, EPA believes it is possible to improve the hazard and exposure assessments that form the basis for understanding pesticide chemical risks. It will take time and substantial research to build this new approach. OPP will incorporate the new technologies into EPA's hazard and risk assessment processes as the technologies are sufficiently developed and peer reviewed. Development and vetting of this new approach to chemical management must be accomplished while continuing to make pesticide registration decisions. Eventually, the new technologies should:

- Create a broader suite of computer-aided methods to better predict potential hazards and exposures, and to focus testing on likely risks of concern.

• Improve the approaches to more traditional toxicity tests to minimize the number of animals used while expanding the amount of information obtained.

• Improve OPP's understanding of toxicity pathways to allow development of non-animal tests that better predict how exposures relate to adverse effects.

• Improve the diagnostic biomonitoring and surveillance methods to detect chemical exposures and identify causes of toxic effects.

Since the publication of the proposed rule in October 2008, OPP announced its strategic direction to move toward an improved testing and assessment paradigm where *in vivo* (animal) testing would be targeted to the most likely hazards of concern. OPP envisions an enhanced testing/assessment paradigm that is a progressive, tiered-testing approach. This paradigm shift should accrue the following benefits to OPP:

• Ability to evaluate more chemicals across a broader range of potential effects in a shorter time frame.

• Potential to increase the feasibility of assessing the risks posed by mixtures.

• Enhanced predictive ability to determine whether animal testing is needed to refine a risk assessment and to inform management decisions.

• Refine and reduce animal testing by maximizing information obtained from animal studies, and focusing on effects of concern.

• Opportunities for improved diagnostic biomonitoring and surveillance methods to detect chemical exposures and identify causes of toxic effects.

• Enhance the quality and efficiency of risk assessment and risk management decisions.

Over the next several years, OPP intends to improve and transform its approach to pesticide risk management by enhancing its ability to use integrated approaches to testing and assessment. The Agency's work on an integrated approach means the development of increasingly effective laboratory animal tests that are designed to maximize the information generated about the nature of the effects being studied. OPP intends to expand its toolbox of predictive models. The new toxicity and exposure approaches will enhance priority-setting and screening approaches and therefore focus Agency and societal resources on those chemicals with the greatest risk potential.

These advances will be incorporated within a risk assessment framework of problem formulation, hazard, dose response, exposure assessment, and risk characterization to support pesticide registration decisions. As this framework evolves, EPA will create pilot programs and develop guidance documents to inform applicants and others of the alternative approaches being used.

It will require many years to realize the NAS vision of a new toxicity paradigm based on evaluating perturbations in cellular pathways by reliance on an array of computational and *in vitro* methods. However, the development and expansion of certain tools used to guide more intelligent *in vivo* testing is anticipated to become available in the nearer term (≤5 years) which includes (Q)SAR/expert systems, TTCs, and *in vitro* technologies. As EPA transitions to the use of these components of intelligent testing or alternative methods, communication will be essential. Through its Pesticide Program Dialog Committee, OPP has created a 21st Century Toxicology/New Integrated Testing Strategies Workgroup. For information, see *http://www.epa.gov/pesticides/ppdc/testing/index.html.*

Additionally, OPP has and will continue to publicly vet this new approach. On May 24–26, 2011, OPP requested that the FIFRA SAP consider and revise a set of scientific issues related to Integrated Approaches to Testing and Assessment (IATA) Strategies: Use of new computational and molecular tools. OPP plans to build on an established foundation of using a variety of tools in a tiered testing and assessment framework by systematically adding new tools and methodologies, as well as an advancing understanding of key events in toxicity pathways. OPP requested the SAP's input on EPA's plans to maximize use of existing data from similar compounds, including information from new toxicity hazard computational and *in vitro* predictive models, and exposure modeling to target *in vivo* toxicity testing that is necessary to assess and manage chemical risks, appropriately. Two case studies illustrated the use of these approaches. The SAP Report is available at *http://www.epa.gov/scipoly/sap/meetings/2011/052411meeting.html#frn.*

VI. Antimicrobial Use Patterns

This unit summarizes the significant public comments and EPA's response to those comments. A more detailed discussion can be found in the Response to Comments Document available in the docket to this rule.

A. Definitions of Use Patterns

1. *Comment.* The commenter suggested different use patterns for EPA to consider. The commenter believes that the use patterns proposed by EPA are not use patterns but descriptions of product types. The commenter suggested six general use patterns for EPA to consider. These include:

• Indoor industrial (all nonfood);

• Indoor residential/commercial/institutional nonfood;

• Indoor commercial/institutional food;

• Aquatic areas nonfood;

• Aquatic areas food;

• Material preservative for exempt treated article uses.

2. *EPA's response.* The Agency disagrees that these suggested use patterns are adequate substitutes for the proposed use patterns. The use patterns that EPA proposed provide a reasonable approach for allowing the Agency to more clearly identify and tailor the data requirements for the different types of antimicrobial pesticides. In some cases, that is best accomplished by using the product type to define the use pattern.

EPA has reviewed the commenters' descriptions of their six suggested general use patterns and has determined that they do not acknowledge all potential exposure pathways of antimicrobial pesticides, particularly those discharged to wastewater as a result of processing and end-use. Although three of the proposed general use patterns include ''indoor'' in the name, the exposure potential for these use patterns is not limited to the indoor environment. This is because these patterns include processes and end-uses of antimicrobial pesticides that are discharged to wastewater, thereby leading to the potential for microorganisms in WWTPs to be exposed to antimicrobial pesticides and for aquatic organisms to be exposed to antimicrobial pesticides in surface water downstream of WWTPs. If the antimicrobial is not completely removed during treatment, exposures of humans to antimicrobials may also be associated with antimicrobials discharged to wastewater that enters WWTPs and subsequently enters surface water via WWTP effluents. Furthermore, there may also be the potential for terrestrial organisms and humans to be exposed to antimicrobial pesticides if the antimicrobial that is discharged to wastewater partitions to biosolids.

Since the processing or end-use of an antimicrobial pesticide in an indoor setting does not preclude the potential for its release to ambient environmental media, particularly under circumstances in which there is potential for discharges of antimicrobial pesticides to wastewater, EPA believes that the designation of an antimicrobial use pattern as ''indoor'' is misleading. Based on the conclusion that processing or

end-use of an antimicrobial pesticide in an indoor setting does not preclude its release to the ambient environment, EPA believes that a down-the-drain analysis is needed for all use patterns with the exception of the aquatic areas use pattern.

The commenter's suggested use patterns are also inconsistent with EPA's reevaluation of the data required for wood preservatives. In response to comments, the Agency determined that all treated wood needs to be considered as having the potential to come into contact with surface water. Therefore, for wood preservatives, EPA has changed several data requirements in both the environmental fate table and the non-target organisms table from ''CR'' to ''R.'' However, under the commenter's six suggested use patterns, wood preservatives would be considered to be the same as material preservatives. The commenter did not differentiate the data needed between the two use patterns. EPA believes that the data needed for a wood preservative is distinctly different from that needed for a materials preservative. Wood preservatives have a high potential for environmental exposure, as evidenced by both environmental fate and nontarget organisms data requirements that are ''R.'' Material preservatives have a lower potential for environmental exposure and consequently are ''CR.'' Thus, the data requirements codified in this final rule acknowledge the differences in the data needed by having two distinctly different use patterns: Wood preservatives and material preservatives.

Given the inclusion of the term ''indoor'' as part of the title of three of the suggested use patterns, and the combining of wood preservatives and materials preservatives into a single use pattern, EPA believes that the six general use patterns suggested by the commenter would not adequately serve EPA's or the public's needs. Additionally, the 1997 review by the FIFRA SAP of EPA's 12 antimicrobial use patterns indicated the SAP's agreement that the Agency's proposed designation of 12 use patterns was a reasonable approach to organizing data requirements, and was, in fact, similar to the approaches used by Canada's Pest Management Regulatory Agency (PMRA), and the California Environmental Protection Agency. Therefore, EPA is codifying the 12 use patterns that were proposed.

B. Wood Preservative Use Pattern

1. *Comment.* Several commenters questioned how wood preservatives were treated in the proposed rule. One commenter thought that all wood preservatives should be considered as having contact with water. Another commenter argued that the industrial, commercial and do-it-yourself uses of wood preservatives are different and should be assessed differently.

2. *EPA's response.* Wood preservatives are pesticides for incorporation into wood products to control wood degradation problems due to fungal rot or decay, sapstain, molds, or wood-destroying insects.

As explained in the proposed rule, (73 FR 59405) EPA's current practice of determining the data required for a wood preservative product is dependent upon where the product is intended to be used (land-only versus land and aquatic). Under this approach, fewer environmental fate and ecological effects studies are required for products that limit their use patterns to land-only uses. This approach also assumes that diversion does not occur and that wood that is treated for land-only uses does not end up in the water and vice versa. EPA specifically requested comments on the regulation of wood preservative products, and indicated that based on the comments received could determine to continue with the current practice of considering land-only applications, or change to a land and aquatic usage. Based on comments indicating that the data required to register a wood preservative should not differentiate between land only and aquatic only applications of treated wood, EPA has reevaluated this approach. As discussed in the proposed rule, it is difficult to assure that diversion does not occur. EPA considered three possibilities:

- Assume all treated wood could have the potential to come into contact with surface water.
- Use an approach similar to that advocated by the American Wood Protection Association (AWPA) approach which differentiates between marine/freshwater and ground contact use/above ground contact use.
- Maintain status-quo.

Wood preservatives used to protect wood structures placed directly in or over water (e.g., marine pilings, docks) will leach active ingredient into the water, resulting in potential exposure of aquatic organisms. Wood preservatives used in the terrestrial environment for uses such as fences, siding, and decks will leach active ingredient into soil where it may be transported into the aquatic environment and expose aquatic organisms.

The Emission Scenario Document (ESD) for Wood Preservatives prepared by the Organisation for Economic Co-operation and Development (OECD) as part of its Series on Emissions Scenario Documents provides guidance on how to estimate emissions of chemical substances in wood preservative products to air, water, and soil as a result both of product application and storage of treated wood prior to shipment and treated wood-in-service. This OECD ESD documents the occurrence of pathways of release of chemical substances during wood preservative application to facility drains that subsequently convey wastewater to WWTPs; entry of chemical substances to adjacent surface water bodies by way of run-off water from unpaved storage of wood preservative-treated products following a rain event; and leaching of chemical substances from in-service uses of treated exterior wood out of ground (i.e., fences, noise barriers), wood in-ground (transmission poles, fence posts), and wood in direct contact with fresh and sea water (poles and planks/decking of jetties and wharfs). Additional information on indirect releases to surface water of antimicrobial pesticides used as wood preservatives can be found in response to comment 134.1 in the Response to Comments Document in the docket.

Given the number of pathways identified that result in potential exposure from treated wood, the Agency determined that all treated wood should be considered as having the potential to come into contact with surface water. All wood preservative risk assessments will now be performed considering that the treated wood could end-up either on the land or in the aquatic environment. As previously discussed, there are multiple pathways for wood preservative degradates and/or leachates to reach surface water. The AWPA approach would have continued the practice of determining the data requirements based on the intended use site of the treated product.

Given this decision, that all treated wood could have the potential to come into contact with surface water, the wood preservative columns of the final Environmental Fate and the Nontarget Organisms Tables were revised.

For the final Environmental Fate Table, for the wood preservatives column, the data requirements for anaerobic soil metabolism, aerobic aquatic metabolism, and anaerobic aquatic metabolism were changed from ''CR'' to ''R.'' Because treated wood products have outdoor usages, the Agency believes that these products have the potential to come into contact with surface water as well as soils which can become flooded or

waterlogged and then be released to surface water.

For the final Nontarget Organism Table, for the wood preservatives column, the data requirements for chronic toxicity testing with fish (fish early-life stage) and aquatic invertebrate (aquatic invertebrate life-cycle) are being changed from ''CR'' to ''R'' to provide chronic data when chronic exposure is expected.

The Agency agrees that the industrial, commercial, and do-it-yourself uses of wood preservatives are different in terms of human exposure. Industrial wood preservative uses are assessed for those workers involved in the actual treatment of the wood with the preservative. This includes operations at a pressure treatment facility where workers add the preservative to treatment cylinders, remove treated wood charges from the cylinders, check the treated wood to verify retention rates, and move the freshly treated wood around the facility (from cylinder to drip pad to storage to shipping). Industrial sapstain wood preservatives are also assessed at the treatment facility for the application of the pesticide. Worker tasks for the non-pressure treatment (non-PT) are slightly different than those at pressure treatment (PT) facilities. Separate exposure measurements unique to each type of treatment (PT vs non-PT) are used in the assessments.

Exposures to commercial and do-it-yourself uses of treated wood are assessed for those installing the treated wood and for those exposed to the treated structures (e.g., play sets and decks).

VII. General and Administrative Issues

This unit summarizes the significant public comments and EPA's response to those comments. A more detailed discussion can be found in the Response to Comments Document available in the docket to this rule.

A. Scientific Advisory Panel (SAP) Waivers

1. *Comment.* A commenter noted that in the preamble to proposed part 158, subpart W, EPA cites multiple SAP reports that did not specifically mention antimicrobial pesticides. Therefore, the commenter believes these SAP reviews were insufficient. Another commenter noted that it has been 9 years since the last SAP review and that EPA should request another SAP review prior to implementation of proposed part 158, subpart W. Still another commenter believes that EPA's request that the SAP waive its review of proposed part 158, subpart W based on the SAP's 1997 review was improper, and that the SAP cannot waive its statutory review obligation.

2. *EPA's response.* EPA disagrees with the comments. On June 3, 1997, EPA presented an early version of the part 158, subpart W proposal in an open meeting to the SAP. At that time, the SAP provided extensive comments in five areas: Toxicology, residue chemistry, ecological effects and environmental fate, human exposure, and efficacy. Since then, the SAP has considered many specific studies and scientific issues included in proposed part 158, subpart W as part of their reviews of guidelines and of data requirements for conventional agricultural pesticides (see the documents identified in the docket by document ID numbers EPA–HQ–OPP–2008–0110–0032, –0033, –0034, –0035, and –0036). In 1997, the SAP also noted its concern about the possible effects of antimicrobials on WWTPs. Partially in response to the SAP comments, EPA proposed a tiered set of environmental fate data requirements that will allow the Agency to better characterize potential incidences of antimicrobials in surface waters, as a result of down-the-drain uses of antimicrobials.

When the Agency prepared to propose 40 CFR part 158, subpart W, EPA requested that the SAP waive its review of the about-to-be-proposed part 158, subpart W because there were no new scientific issues. The SAP waived its review of the about-to-be proposed part 158, subpart W on February 19, 2008. The Agency continues to believe that there are no new scientific issues that warrant additional review by the SAP. EPA's request for a SAP waiver for the final antimicrobial data requirements rule is discussed in Unit XXIV. FIFRA section 25 requires EPA to give the SAP at least 60 days to review proposed regulations and 30 days to review final regulations. However, the SAP can determine to waive its review during the statutory time periods.

B. Risk Assessments for Wood Preservatives

1. *Comment.* A commenter noted that Canada's PMRA and USEPA conduct risk assessment for wood preservatives differently. EPA's risk assessment is based on the treated wood when used at the final use site, while the PMRA's risk assessment is based at the site where the wood is treated. The PMRA also does not distinguish between terrestrial-only or aquatic-only use for anti-sapstains and heavy-duty wood preservatives.

2. *EPA's response.* The Agency acknowledges differences between its risk assessment of wood preservatives and that of Canada's PMRA. As previously discussed in Unit VI.A. and B., EPA has reevaluated its approach for determining the data required for a wood preservative product. As part of the reevaluation, EPA considered the human and ecological risks based on exposure pathways identified in OECD's ESD for Wood Preservatives. This ESD identifies potential human and ecological exposures from both treatment of wood at processing facilities and in-service uses on land and in water. The Agency determined that all treated wood should be considered as having the potential to come into contact with surface water. This determination reflects EPA's concern about the potential for the indirect release to surface waters of wood preservatives. As a result, EPA is changing its approach to requiring environmental and ecological effects studies for wood preservatives. All wood preservative risk assessments will now be performed considering that the treated wood could end-up either on the land or in the aquatic environment, thus increasing harmonization between PMRA and EPA with regard to wood preservatives.

C. Clarity on How and When CR Data is Required

1. *Comment.* A commenter asked EPA to specify criteria to determine whether a data requirement is ''R'' (Required) or ''CR'' (Conditionally Required). According to the commenter, the discussion of ''R'' and ''CR'' suggests that a data requirement labeled ''CR'' may not be required to be addressed by the applicant. A second commenter stated that it is unclear how and when conditionally required data are triggered. Another commenter asserted that data requirements should be waived only under extraordinary circumstances, and that the use of waivers can effectively preclude appropriate regulation of the pesticide under FIFRA.

2. *EPA's response.* In its proposed data requirement tables, EPA specified whether a data requirement is ''Required'', ''Conditionally Required'', or ''Not Required'' based on how likely the study is needed to complete an assessment of an antimicrobial pesticide. As a rule of thumb, a ''Required'' study is likely to be needed 50 percent of the time or more and a ''Conditionally Required'' study is likely to be needed less than 50 percent of the time. Typically, a ''Conditionally Required'' study is triggered based on the results of a study that has already been conducted. Triggers in the test notes indicate the circumstances under

which the Agency has learned through experience that the information is needed. In many instances, the applicant would be able to make the determination that the trigger has been met and should include the data in their original submission. In other cases, EPA will make the determination based on its review of submitted data and would then request additional data from the applicant. EPA encourages applicants to consult with the Agency to determine the actual need for the data.

All data requirements must be addressed by the applicant by either conducting the study or submitting information that could fulfill the data requirement, such as citing open literature or other data sources, or by requesting and receiving a data waiver. EPA grants data waiver requests only on a case-by-case basis and only when the available evidence indicates a particular study is not needed or that there are particular reasons for not conducting the study. For example, if the physical/chemical properties of the chemical did not lend themselves to the testing procedure, such as performing an inhalation study with a chemical that is a solid and has an extremely low vapor pressure, then a waiver might be granted. EPA also grants waivers in exceptional circumstances, for instance, if a test substance is so corrosive that animal studies would cause undue pain and suffering.

VIII. Product Chemistry

The following represent the significant comments received on the need for and evaluation of product chemistry studies as proposed by EPA. A more detailed discussion can be found in the Response to Comments Document available in the docket to this rule.

A. Application of Subpart D Product Chemistry Data Requirements to Antimicrobials

1. *Comment.* A commenter requested that EPA provide adequate justification for applying the existing product chemistry data requirements for conventional pesticides to antimicrobials without consideration of the highly dissimilar chemistries and inapplicability of many of the requirements.

2. *EPA's response.* It has been EPA's longstanding practice to require product chemistry data. Product chemistry data are required to identify the chemicals used to manufacture a product and to understand the physical and chemical properties of the ingredient or product. Such information is generally independent of the intended use pattern. Product chemistry data are used during label development to identify information to be included on the label, such as the flammability statement, and directions for disposal of the product. Hence, despite any differences between conventional and antimicrobial pesticides, the Agency believes it is appropriate to apply the same product chemistry data requirements to antimicrobials as required for conventional pesticides. The guidelines for conducting product chemistry studies offer flexibility to account for differences between chemical classes.

B. Lack of Adequate Opportunity for Review of Product Chemistry Data Requirements

1. *Comment.* One commenter asserted that registrants of antimicrobial pesticides were not given the opportunity to review and comment on conventional pesticide data requirements that are now being proposed for antimicrobial pesticides.

2. *EPA's response.* In the preamble to proposed part 158, subpart W, EPA proposed to apply the product chemistry data requirements for conventionals in 40 CFR part 158 subpart D to antimicrobial pesticides. Therefore, during the public comment period for proposed part 158, subpart W, from October 8, 2008, to April 6, 2009, any interested party could have commented on the product chemistry data requirements in subpart D (which have been in place since October 2007) and their potential applicability to antimicrobials.

IX. Product Performance Data Requirements

The following represent the significant comments received on the need for and evaluation of product performance studies as proposed by EPA. Changes from the proposed rule to the final rule are also described. A more detailed discussion can be found in the Response to Comments Document available in the docket to this rule.

A. Product Performance Guidelines

1. *Comment.* Several commenters shared their belief that EPA was seeking to avoid comment on the product performance data requirements in the proposed rule by stating that the Agency ''is not proposing to revise product performance data requirements'' at this time. Another commenter asked how the product performance section of the proposed rule could be finalized without the 810 guidelines?

2. *EPA's response.* The proposed product performance data requirements table referenced the older 91 series guidelines. As stated in the proposed rule, the requirements being proposed were ''nearly identical'' to the existing data requirements in § 158.400 and 161.640, and the table was ''transferred essentially unchanged'' (73 FR 59391). Since the 2008 proposed rule, EPA published four of the 810 series guidelines (810.2000, 810.2100, 810.2200, and 810.2300 for sterilants, disinfectants and sanitizers) for comment in the **Federal Register** of January 27, 2010 (75 FR 4380) (FRL–8437–2), indicating that these guidelines would be incorporated into the final rule for antimicrobial data requirements. Three additional product performance guidelines (810.2400, 810.2500, and 810.2600) were published for public comment on September 15, 2011 (76 FR 57031) (FRL–8879–1). Thus, in addition to commenting on the draft guidelines themselves, commenters had an opportunity to comment on the inclusion of the 810 series in the Product Performance Data Requirements table.

The availability of the final guidelines for sterilants, disinfectants and sanitizers (810.2000, 810.2100, 810.2200, and 810.2300) was announced in the **Federal Register** of March 16, 2012 (77 FR 15750) (FRL–9332–4), and for the three additional product performance guidelines (810.2400, 810.2500, and 810.2600) in the **Federal Register** of June 27, 2012 (77 FR 38280) (FRL–9349–5).

In this final rule, EPA is replacing the 91 series designations proposed in the part 158, subpart W product performance table with the appropriate 810 series guideline numbers and names. The 810 series guidelines represent the Agency's current recommendations for conducting product performance studies to support antimicrobial pesticide label claims. See Unit XVIII for a discussion on guidelines.

B. Emerging Pathogens

1. *Comment.* A commenter asked why there is no formal regulatory practice for registering products to address public health emergencies or emerging pathogens promptly and effectively?

2. *EPA's response.* EPA does not believe that the promulgation of a rule dealing with data requirements is the appropriate place to address emerging pathogens. A major consideration in the Agency's process for addressing public health emergencies and emerging pathogens is to work closely with the Centers for Disease Control and Prevention (CDC), USDA, and FDA, as appropriate, to provide a timely and accurate response to these situations.

Under FIFRA section 18, the Agency also has authority to grant certain exemptions from the provisions of FIFRA and also to approve the use of unregistered pesticides when emergency conditions exist. Additionally, in April 2008, the Agency implemented a disinfection hierarchy policy for addressing emerging viral pathogens. Information on this policy is available on the EPA Web site at *http://www.epa.gov/oppad001/disinfection_hier.htm.* EPA believes that emerging pathogens require flexibility and speed in disseminating information and seeks to address such situations in a prompt and effective manner.

C. Definitions of Sanitizer and Disinfectant

1. *Comment.* Several commenters claimed that the proposed definitions do not reflect the work done by the regulated community in cooperation with EPA since 1999. In particular, these commenters did not agree with the proposed definitions of sanitizer and disinfectant.

2. *EPA's response.* Since the publication of the proposed rule, the definitions, including those for sanitizer and disinfectant, were published in the **Federal Register** for public comment on January 27, 2010, as part of requesting comment on draft guideline 810.2000. After further review of the comments submitted on the proposed definition for disinfectant and sanitizer, the Agency has revised the definitions that had been proposed for both part 158, subpart W and the 810 Guidelines. EPA believes that the definitions being codified in part 158, subpart W reflect the input received from the regulated community in multiple submissions.

The definition for disinfectant is being revised from, ''Disinfectant means a substance, or mixture of substances that destroys or eliminates a specific species of infectious or public health microorganism, but not necessarily bacterial spores, in the inanimate environment'' to read, ''Disinfectant means a substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment.''

The definition for sanitizer is being revised from, ''Sanitizer means a substance, or mixture of substances that reduces the bacterial population in the inanimate environment by significant numbers, but does not destroy or eliminate all bacteria or other microorganisms'' to read, ''Sanitizer means a substance, or mixture of substances that reduces the bacterial population in the inanimate environment by significant numbers, but does not destroy or eliminate all bacteria. Sanitizers meeting Public Health Ordinances are generally used on food contact surfaces and are termed sanitizing rinses.'' A 3 $\log_{10}$ reduction is the minimum log reduction needed to make a non-food contact surface sanitizing label claim, and is considered a significant reduction.

The definitions for fungicide, sterilant, tuberculocide and virucide are being revised to include the following phrase: ''or mixture of substances.'' Inclusion of this phrase in all of the definitions in § 158.2203 for types of products that bear public health claims (excepting microbiological water purifier) means consistency in the definitions and an acknowledgement that the destroying, reducing, or inactivating may be accomplished via more than a single substance. Also, this makes these definitions similar to the FIFRA section 2(u) definition of pesticide which also contains the phrase ''or mixture of substances.''

Additionally, the definition for virucide is being revised to include the word irreversibly, as follows: ''Virucide means a substance, or mixture of substances, that destroys or irreversibly inactivates viruses in the inanimate environment,'' thus reading similar to the definition for tuberculocide. Additionally, the definition for sterilant will be revised to remove the second sentence of the proposed definition: ''For purposes of this subpart, 'sporicide' and 'sterilant' are synonymous.'' EPA no longer requires that products that make sporicidal claims also make sterilant claims.

D. Nonpublic Health Data and Claims

1. *Comment.* A commenter asked that the issue of when to generate efficacy data for nonpublic health products be discussed, since registrants are required to develop data to substantiate label claims. 2. *EPA's response.* The Agency believes this issue has been addressed in § 158.2220 ''Product Performance,'' which clearly states, ''Each applicant must ensure through testing that his product is efficacious when used in accordance with label directions and commonly accepted pest control practices.'' However, to clarify the issue further, the Agency is adding a definition for nonpublic health claims that will appear as 40 CFR 158.2204(b). Additionally, EPA is revising 40 CFR 158.2220(a)(3) to describe that products bearing a nonpublic health claim are to be supported by product performance data.

Also, EPA has posted on the Antimicrobials Division Web site the parts of the 91 Guideline series that apply to testing of nonpublic health products. Although these guidelines are from 1982, they are still relied on to develop data to support label claims for nonpublic health products. EPA acknowledges that some of the references in the 1982 guidelines are to the older 91 series guidelines, which is being replaced by the 810 series guidelines. To assist readers, EPA has also posted a cross-walk table so readers can locate the applicable section of the 810 Guidelines. For information, see *http://www.epa.gov/oppad001/non-public-health.html.*

X. Toxicology Data Requirements

The following represent the significant comments received on the need for and evaluation of toxicology studies as proposed by EPA. Changes from the proposed rule to the final rule are also described. A more detailed discussion can be found in the Response to Comments Document available in the docket to this rule.

A. Threshold of Toxicological Concern Approach

1. *Comment.* There should be a threshold of toxicological concern (TTC) type of approach for antimicrobials.

2. *EPA's response.* OPP's Antimicrobials Division is aware of the TTC concept. ILSI is currently pursuing the development of an application of the TTC concept to evaluate antimicrobial pesticides. Development and peer review of a TTC approach for antimicrobials is expected to occur over the next 1 to 2 years. Based on expert peer review and public comment, the Agency will make decisions regarding implementation.

B. Test Note to Neurotoxicity Studies

1. *Comment.* A commenter stated that proposed test note 6 to the proposed toxicology table in § 158.2230 triggering the neurotoxicity studies is contradictory and unclear. The commenter asked how the absence of a neurotoxicity screen in the 90-day oral rodent study would impact proposed test note 6?

2. *EPA's response.* Proposed test note 6 specifies that if the neurotoxicity screen that occurs in the 90-day oral rodent study or any other data demonstrate neurotoxic effects, then both the acute neurotoxicity study and the 90-day neurotoxicity study are triggered. For certain use patterns with the potential for larger exposures (most notably food exposures), all three of these studies are initially required. According to proposed test note 8 to the proposed toxicology table in § 158.2230,

the applicant may combine the 90-day oral toxicity study and the 90-day neurotoxicity study by adding a separate group of test animals.

However, for some use patterns, the 90-day oral study is required, and the other two studies are conditionally required, being triggered by proposed test note 6. EPA acknowledges that when only the 90-day oral study is required, an applicant is at a disadvantage in terms of any chance for combining the 90-day neurotoxicity study with the oral study: Once the 90-day oral study with its neurotoxicity screen has been performed, and neurotoxic effects are identified, then it is not possible to add a separate group of test animals to the already conducted study.

As a point of clarification, EPA is adding a new test note to the final toxicology table in § 158.2230(g) to clarify that the neurotoxicity screen that is part of the 90-day oral study is not equivalent to a 90-day neurotoxicity study. If the 90-day oral toxicity study does not have a neurotoxicity screen, then the acute neurotoxicity study in the rat would be required. The new test note also includes: ''if the 90-day oral rodent study does not include a neurotoxicity screen, then the acute neurotoxicity study will be required.'' As part of renumbering, this new test note is now test note 11 to the toxicology table in § 158.2230(g) in this final rule.

C. End-Product Use-Dilution Toxicity Testing

1. *Comment.* Several commenters stated their belief that acute end product use-dilution toxicity testing should be optional and requested greater clarification on when to test a diluted product. The commenters asked whether extrapolation from the active ingredient or as-sold acute toxicity testing is acceptable? Another commenter claimed that requiring end-product six-pack testing of one or more dilutions is duplicative.

2. *EPA's response.* Proposed test note 2 to the proposed toxicology table in § 158.2230, specifies how to conduct acute toxicity testing for end-use products (EP). EP testing is conducted on the product as formulated for sale and distribution. From the EP acute toxicity studies, EPA derives toxicity categories which are then used to determine the precautionary labeling statements on the product. However, it is common for some products to be diluted before being used. The use-dilution testing is in addition to the as-formulated-for-sale testing since there are exposures to both. Acute toxicity testing on the product that has been diluted-for-use supplies the information needed to derive precautionary statements for the user of the product. EPA is revising proposed test note 2 to make this clearer.

D. The Phrasing ''Limited Portion of the Human Lifespan''

1. *Comment.* Several commenters asked EPA to identify the criteria to determine ''repeated human exposure over a limited portion of the human life span.'' They asked EPA to specifically describe what the phrase ''human exposure is not purposeful'' means?

2. *EPA's response.* Proposed test note 11 to the proposed toxicology table in § 158.2230, specifies the triggers that would require the performance of a 90-day oral study in the non-rodent. EPA has reevaluated this test note and decided not to codify test note 11, as proposed, Proposed test note 11, subparagraph i. contained the phrase ''repeated human exposure over a limited portion of the human life span.'' EPA agrees that this phrase is not useful. Proposed test note 11, subparagraph ii. contained a trigger for any indirect food use that would have been considered to be a ''low exposure.'' Given the restructuring of the final toxicity data requirements table, i.e., the shift away from using high and low exposure as the table headers to a food/nonfood approach, test notes 11, subparagraphs i. and ii. are no longer needed. In the final toxicity table in § 158.2230(g), the data required for an indirect food-use is specified directly (in the table header) and a trigger is not needed.

Test note 12 to the proposed toxicology table in § 158.2230, specifies three triggers that would require the performance of a 21/28-day dermal study. EPA has also reevaluated proposed test note 12 and agrees that the phrases ''repeated human exposure over a limited portion of the human life span'' and ''human exposure is not purposeful'' are not useful. Accordingly, EPA has revised the 21/28 day dermal study trigger. The 21/28 day dermal study is now triggered if all of the following criteria are met:

i. The intended use of the antimicrobial pesticide product is expected to result in repeated dermal human exposure to the product;

ii. Data from a 90-day dermal toxicity study are not available;

iii. The 90-day dermal toxicity study has not been triggered (the third proposed trigger).

E. Mouse Carcinogenicity Study

1. *Comment.* According to several commenters, the mouse carcinogenicity study does not provide useful information, and is, in fact, not suited for determining/extrapolating human carcinogenicity. They contended that EPA should no longer require the mouse carcinogenicity study. This would also mean that there is no need for the mouse range-finding study.

2. *EPA's response.* The issue regarding the usefulness of the mouse for carcinogenicity testing is one that is currently under debate by the OPP. Currently, carcinogenicity testing, whether for conventional pesticides under § 158.500 or for antimicrobials under part 158, subpart W requires testing in two rodent species. However, OPP is currently conducting a comprehensive analysis of its rodent chronic bioassay database to document the utility of the mouse bioassay for both cancer risk assessment and Reference Dose (RfD) derivation for non-cancer endpoints. When this analysis is completed, a recommendation will be made regarding the testing needed for cancer hazard identification. Once OPP's internal review process is complete, then it is likely that EPA would solicit review and comment by the FIFRA SAP. If at a later date, the determination is made to alter the carcinogenicity data requirements, then appropriate changes would be proposed to be made to data requirements and regulations pertaining to conventionals, biochemicals and microbials, and antimicrobials through rulemaking.

F. Ames Assay

1. *Comment.* A commenter argued that the Ames assay should not be required, because it is inappropriate for antimicrobials that kill bacteria.

2. *EPA's response.* It is recognized that the Ames assay may not be useful for assessment of mutagenic potential of antimicrobial pesticides, as this test uses strains of bacteria as the primary test material, and antimicrobials are designed to kill, among other things, bacteria. So, the bacteria may be killed before mutagenic effects are demonstrated. However, for some antimicrobial pesticides, the Ames assay has already been conducted and if the Ames assay was conducted at levels that do not cause toxicity to the bacterial strains tested, then the study may be acceptable to fulfill the reverse mutation assay requirement. However, if an Ames assay has not yet been conducted for a particular antimicrobial, then, the Ames assay should not be conducted. In this final rule, test note 32 for the reverse

mutation assay requirement in the final toxicology table in § 158.2230(g), is revised to allow reliance on previously-conducted Ames tests when the bacteria strain was not killed, but to state a preference for assays such as an *in vitro* mammalian cell assay, (e.g., the mouse lymphoma TK +/− assay).

G. Dermal Absorption Studies

1. *Comment.* A commenter argued that EPA should accept *in vitro* skin penetration data. According to the commenter, accepting such data would harmonize with requirements in the European Union (EU) and elsewhere. The commenter pointed to well-established OECD guidelines for these studies. The commenter also asserted that proposed test note 37 to the proposed toxicology table in § 158.2230, addressing the requirement for a dermal absorption study, should not apply to corrosive/irritant products.

2. *EPA's response.* The Agency has, on a case-by-case basis, used *in vitro* dermal absorption studies to determine the magnitude of dermal absorption of pesticide chemicals. However, the Agency has not adopted an official policy of using only *in vitro* data to support these decisions. OECD guideline 428, while describing an *in vitro* method for dermal absorption, does not rule out the use of *in vivo* data along with *in vitro* data to determine dermal absorption. Further, the test guideline notes that formal validation studies of the *in vitro* method have not been performed.

The Agency is working on developing a more formal policy that would use both *in vivo* and *in vitro* dermal penetration data in a weight-of-evidence (WOE) determination in appropriate cases. The Agency would always consider QSAR or other models, submitted in support of the determination of dermal absorption. The decision to accept such information is the Agency's, based on its review and evaluation of the submission.

Test note 37 to the proposed toxicology table in § 158.2230, specifies that the trigger for requiring a dermal penetration study are the results from a risk assessment ''assuming that dermal absorption is equal to oral absorption.'' This means that EPA assumes 100 percent dermal absorption. If a subchronic dermal study and/or dermal absorption data are not available, then a risk assessment could be conducted using the default assumption of equivalent absorption by the dermal and oral routes of exposure. If unacceptable risks are found, then either the subchronic dermal study or a dermal absorption study would be required. EPA recognizes that the assumption of 100 percent dermal absorption is conservative; however, this assumption would only be used in the absence of an acceptable dermal subchronic study or dermal absorption data. In this final rule, test note 37 to the toxicology table in § 158.2230(g), is revised to clarify this process. EPA also agrees that corrosive/irritant products should not be tested in dermal absorption studies. Therefore, test note 3 to the toxicology table in § 158.2230(g), which specifies that testing is not needed for corrosive materials, is added as a trigger for not requiring the dermal absorption study.

H. Tiering

1. *Comment.* One commenter argued that EPA has not provided meaningful tiering for its toxicology requirements for antimicrobials. Another commenter claimed that exposure alone is not an appropriate criterion to use for a tiered testing scheme, that both exposure and risk should be considered. A third commenter asserted that the high and low human exposure categories for toxicity are not appropriate and suggested that a tiered scheme such as that used for environmental fate data requirements would be more appropriate.

2. *EPA's response.* In its proposed rule EPA proposed a tiered testing scheme for toxicology testing that was based on the amount of exposure as defined by use patterns. Based on its experience in conducting risk assessments, EPA understands which use patterns have exposures of higher duration and magnitude, and therefore could have greater risks. Use patterns with higher exposures require submission of more data than use patterns with lower exposures.

I. Guideline Numbers in the Code of Federal Regulations

1. *Comment.* A commenter stated that the final rule should not specify a guideline number. Instead, the data requirement tables should describe the endpoint in question, and the information needed for EPA's risk assessment. OPP could develop guidance that could be placed on the web.

2. *EPA's response.* The guideline number column could be removed from the table. Instead, EPA could have an internet page that describes multiple methods of fulfilling the data requirements. An internet table could be updated faster to reflect newer techniques than rulemaking to revise a regulation in the CFR. However, there is also value in having the guideline number in the CFR, which then shows the available guidelines relevant to the particular study that should be considered in addressing the requirement. EPA has made no decision on whether or not to initiate a rulemaking to remove all the guideline numbers from the data requirement tables in 40 CFR part 158. The tables finalized in subpart W in this rule include guideline numbers.

J. Animal Testing

1. *Comment.* A commenter requested that EPA specifically state in its regulations that non-animal methods are acceptable for fulfilling a data requirement. The commenter argued that the Draize study (the acute eye irritation study) in rabbits should be eliminated.

2. *EPA's response.* Non-animal test methods are continually being examined for use in fulfilling the toxicology data requirements that are used to assess the hazard of pesticide chemicals. However, in order for non-animal approaches to be used for fulfilling toxicology data requirements, these approaches must first be scientifically validated to ensure that they are as good as the existing test method for predicting hazard and also assessed to determine whether they meet the Agency's ''3 R'' goals of reduce, refine, and replace the use of animals in testing. With respect to antimicrobial pesticides, the Agency has started to explore such approaches. One example of this is the voluntary pilot program for eye irritation testing of antimicrobial pesticides using non-animal test methods, found at *http://www.epa.gov/oppad001/eye-irritation.pdf.*

K. Derivation of 200 Parts per Billion Criterion

1. *Comment.* A commenter asked whether the 200 parts per billion (ppb) level used as the dividing line between high and low human exposures is the concentration of a substance in an adult's daily food consumption?

2. *EPA's response.* The derivation of the 200 ppb level was previously established by FDA for indirect food use biocides (identified in the docket by document ID number EPA–HQ–OPP–2008–0110–0010). FDA derived the 200 ppb level by dividing the cumulative exposure upper limit of 1,000 ppb for food contact substances by 5 to account for the fact that antimicrobial pesticides (e.g., biocides) are a class of pesticide that are generally toxic by design. The 200 ppb level is the concentration of the antimicrobial residues in or on the food item. EPA is using 200 ppb as a delineation consistent with the FDA's

toxicology recommendations for food contact substances. Therefore, those indirect food uses that have residues that are less than or equal to 200 ppb in or on the food item usually have fewer data requirements than those that have residues that are greater than 200 ppb in or on the food item. For clarity, information concerning the 200 ppb level and its derivation from FDA levels has been added to § 158.2230(d).

L. Use of OECD Guidelines for EPA Registrations

1. *Comment.* A commenter asked EPA to consider incorporating the following OECD guidelines into the new part 158, subpart W to reduce the number of animals killed in LD_{50} tests: OECD guidelines 436; Acute Inhalation Toxicity—Acute Toxic Class Method, and revised 223; Avian Acute Oral Toxicity Test, and Short Guidance on the Threshold Approach for Acute Fish Toxicity.

2. *EPA's response.* OPP does not have a policy for use of OECD 436 for acute inhalation toxicity. If a study conducted according to OECD 436 were submitted for the purpose of assessing acute inhalation toxicity, EPA would review and accept the results if the study were conducted in an acceptable manner and provided sufficient information to fulfill the data requirement. Similarly, if a study conducted according to OECD 223 or the Threshold Approach, were submitted, then EPA would review the study and then make a determination on whether the study was conducted in an acceptable manner and provided sufficient information to fulfill the data requirement.

M. Alternative Formats for Toxicology Data Requirements Table

1. *Comment.* In the comments submitted to EPA, the commenters suggested two alternative toxicity data requirement approaches for EPA to consider. Alternative approach 1 was organized in paragraphs and alternative approach 2 was in a table format similar to that proposed by EPA.

2. *EPA's response.* The commenters provided two alternative approaches for toxicology data requirements for antimicrobials. As stated by the commenter, alternative approach 1 was ''intended to provide clearer instructions to registrants,'' attempted ''to fully incorporate the new science'' of integrative approaches to testing, and included ''a threshold concept for toxicological concerns.'' (ACC Comment, identified in the docket by document ID number EPA–HQ–OPP–2008–0110–0088.6; Appendix E, entitled ''Comments on Proposed Data Requirements for Toxicology'' p. 24). The commenter did not provide to EPA the same or similar table-type of format used for part 158 data requirements. There were no test notes to define the triggers for moving from tier to tier. The commenter acknowledged that their suggested alternative approach 1 would require ''expert scientific judgment'' (p. 25), and also discussed that EPA in the proposed rule (73 FR 59423) had indicated the need to develop scientific position papers, and recommendations for internal and external review of integrative approaches. EPA considers alternative approach 1 to be a dramatic departure from EPA's proposal, and agrees with the commenter that certain scientific issues may not be ready for codification. EPA does not believe, at this time, that this approach meets the needs of the Agency, or has any advantages over the table format. EPA found the paragraph explanations unclear. As acknowledged by the commenter, the paragraph format would result in a more complex decision tree that would require a significantly greater amount of interpretation and consultation when compared to the existing table formats. There would be a significant learning curve for both EPA and those members of the public that have become accustomed to data requirement tables such as in part 158. Within this response, EPA has responded to alternative approach 1 in totality. EPA notes that the individual scientific issues raised within the paragraphs are addressed separately, as they were separated into the various disciplinary areas of the toxicology comments.

EPA has also evaluated alternative approach 2. This alternative approach is in a table-type of format with a strict split between food and nonfood uses. The test notes developed by the commenters are extremely detailed and contain information that EPA believes is more appropriate in guidance. However EPA has used the suggested test notes to revise the test notes in this final rule as appropriate. For example, the commenters' suggested test note 32 to the *in vivo* cytogenetics study is clearer than EPA's proposed test note 34. Therefore EPA is revising test note 34 to the final toxicology table in § 158.2230(g), accordingly.

As discussed previously, as a result of comments received, EPA is no longer using the terms ''high human exposure'' and ''low human exposure'' as proposed for the antimicrobial toxicology data requirements table. Instead, in the final rule, EPA is now using a food/nonfood approach with some similarities to that of the toxicology data requirements table for conventional pesticides to distinguish the use patterns with higher exposure that need more toxicity data from those that need less. Accordingly, the table headers for the toxicology data requirements table in the final rule are: ''Direct Food Uses;'' ''Indirect Food Uses (>200 ppb);'' ''Indirect Food Uses (≤200 ppb);'' ''Swimming Pools, Aquatic Areas, Wood Preservatives, Metal Working Fluids;'' and ''All Other Nonfood Uses.''

Unlike conventional pesticide chemicals, a strict food/nonfood use ''split'' for delineating data requirements is not appropriate for antimicrobial chemicals. Such an approach does not fully address the unique use patterns for antimicrobials, most specifically, those involving indirect food uses. As a result of comments received, EPA decided to employ a modification of the food/nonfood approach to delineate the specific data requirement needs for antimicrobial pesticides.

The commenter has also asked that EPA include within subpart W a new § 158.2235 which would be analogous to 40 CFR 158.510 for conventional chemicals (Tiered Testing Options for Nonfood Use Pesticides). EPA does not believe this is needed for antimicrobials. Once it has been determined that the use is nonfood, then certain of the nonfood use scenarios require the submission of more data, and certain require the submission of less data. As specified in the column headings for Nonfood Uses, swimming pools, aquatic areas, wood preservatives, and metal working fluids require a particular set of data. All other nonfood uses require less data. Thus, the tiering is already built into the approach used for antimicrobials.

XI. Nontarget Organism Data Requirements

The following represent the significant comments received on the need for and evaluation of nontarget organism studies as proposed by EPA. Changes from the proposed rule to the final rule are also described. A more detailed discussion can be found in the Response to Comments Document available in the docket to this rule.

A. Need for Ecotoxicity Data for Indoor Uses

1. *Comment.* Several commenters argued that there are few antimicrobial use patterns where ecological effects information would be relevant to an assessment under FIFRA because there is no expectation of environmental exposure.

2. *EPA's response.* As explained in the proposed rule, there is now a greater concern regarding indoor uses of antimicrobials because those uses can lead to environmental exposure when they go down the drain. The Agency and the scientific community have become concerned with pharmaceuticals and personal care products (PPCPs), which are now recognized as environmental contaminants. A subset of these PPCPs includes antimicrobial pesticide products, some of which are being detected in various environmental compartments/media [e.g., surface water and WWTP biosolids]. As discussed in the proposed rule (73 FR 59407), these findings are notable, because many of the antimicrobial pesticides detected are registered for only indoor use patterns.

There are many uses for which a high potential for environmental exposure exists, especially outdoor uses such as wood preservatives, ballast water treatments, antifoulant paints and coatings, aquatic areas, and others. These uses may require a more extensive data set that could include acute and chronic tests in both freshwater and saltwater, and possibly in the sediment as well as the water column. If the effluent from a WWTP is likely to contain an antimicrobial pesticide, or if the antimicrobial is likely to partition to the sludge that is derived during the treatment process, then indoor uses could require additional testing to further characterize the hazard and the risk.

B. Transformation Products

1. *Comment.* Several commenters questioned, how a registrant would determine if ''transformation products'' would need to be tested. With regard to the criteria for when testing is required on transformation products, another commenter stated the belief that any data developed to assess the potential risk to nontarget organisms should be developed with the appropriate residue of concern (ROC) (i.e., degradation product, metabolite, or TGAI) rather than always testing with the TGAI. Still another commenter asked how would EPA determine that the transformation products are ''more toxic, persistent, bioaccumulative or have been shown to cause adverse effects in mammalian or aquatic reproductive studies.'' Finally, a commenter requested that EPA explain what is considered ''stable'' in the environment in proposed test note 3 to the proposed nontarget organism table in § 158.2240.

2. EPA's response. The Agency evaluates the need for nontarget organism testing of transformation products on a case-by-case basis, using several sources of information, which includes, most importantly, environmental fate data. EPA proposed to require nontarget organism testing of transformation/degradation products or leachate residues in proposed § 158.2240(a)(3) and (4). To respond to this comment, EPA also considered a similar comment on transformation/degradation products or leachate residues for environmental fate testing (see Unit XIV.B.). In response to these comments, EPA determined to clarify and revise the criteria for testing of transformation/degradation products and leachate residues for nontarget organisms in § 158.2240(a)(3), for environmental fate in § 158.2280(a)(2) and for nontarget plant protection in § 158.2250(b).

As explained in Unit XIV.B., environmental fate studies provide information on the stability and persistence of the active ingredient and degradation products in the various environmental media. If the environmental fate studies on the parent indicate the transformation/degradation product(s) is, for example, more persistent in soils, then it is possible that nontarget plants or animals could be exposed to the degradate. Once the transformation products and the environmental compartment in which they occur are identified, then the available toxicology data (e.g., reproduction tests, developmental tests, non-rodent chronic studies) are reviewed to determine toxicity.

After reviewing all available information, then EPA would use these criteria to determine if ecological effects data on the transformation/degradation products or leachate residues are required for either nontarget organisms or nontarget plants. EPA believes that nontarget plant protection data may sometimes be needed when the Agency begins conducting species-specific endangered species assessments for antimicrobial pesticides.

EPA does not use the term ''residue of concern (ROC)'' in the final Nontarget Organisms Data Requirements Table. Instead, the appropriate test material(s), such as TGAI, degradate, or TEP, is specified in the data requirements table in § 158.2240. This approach is also used for the conventional nontarget organism table in part 158. Generally, for ecological testing, the TGAI testing is performed first, and then additional testing on a transformation product may be required based on the process described previously. Depending on how fast a substance decays, a nontarget organism or plant could actually be exposed to a mixture of the parent and one or more degradation/transformation products.

C. Test Note 7 to the Nontarget Organism Table and Wood Preservatives

1. *Comment.* Test note 7 to the proposed nontarget organism data requirements table in § 158.2240 specifies the triggers for requiring typical end-use product (TEP) testing for the acute freshwater invertebrate study and acute freshwater fish study. A commenter asked whether, even though, the wood preservatives use pattern is specified as ''NR,'' could the TEP testing be required because of the triggers in test note 7.

2. *EPA's response.* Proposed test note 7 also triggered the testing for the TEP acute estuarine and marine organisms toxicity testing. EPA agrees that the combination of ''R''s, ''CR''s, ''NR''s and the current structure of proposed test note 7, is confusing and that clarification is needed.

The data requirements for TEP testing and proposed test note 7 were also considered in light of the Agency's determination based on comments received (see Unit VI.B.) on EPA's current practice of conducting risk assessments for wood preservatives based on land-only versus a land and aquatic predetermined use pattern. All wood preservative risk assessments will now be performed considering that the treated wood could end-up on both the land or in the aquatic environment. As previously discussed, there are multiple pathways for wood preservative degradates and/or leachates to reach surface water. EPA has also determined to conduct a down-the-drain assessment for all appropriate use patterns which would include wood preservatives, and antifoulant paints and coatings (see Unit XV.A.). For wood preservatives, these determinations mean that additional ecological testing is required to conduct an ecological risk assessment, and the following changes are made to the wood preservative testing column:

- Acute freshwater invertebrates toxicity (TEP testing): change from ''NR'' to ''CR'';
- Acute freshwater fish toxicity (TEP testing): change from ''NR'' to ''CR'';
- Acute estuarine and marine organisms toxicity (TEP testing): change from ''NR'' to ''CR''.

For antifoulant paints and coatings, the determination to conduct assessment also means that additional data could be needed for the down-the-drain assessment, and the following changes have been made to the antifoulant paints and coatings testing column:

• Acute freshwater invertebrates toxicity (TEP testing): change from ''NR'' to ''CR'';
• Acute freshwater fish toxicity (TEP testing): change from ''NR'' to ''CR'';
• Acute estuarine and marine organisms toxicity (TEP testing): change from ''NR'' to ''CR''.

EPA believes that simplifying the data requirements that reference test note 7 to the final nontarget organism table in § 158.2240(c) so that these requirements are CR for all use patterns is clearer, and also closer to the suggestions made by the commenters in their suggested nontarget organism data requirements table. Their suggested table was predominantly ''CR'' for aquatic uses. Therefore, in this final rule, test note 7 triggers the ''CR'' studies.

However, changing all the use patterns to ''CR'' for the TEP studies means changing the ''R'' proposed for the aquatic use, and industrial processes and water systems use patterns for the acute freshwater invertebrates toxicity study and the acute freshwater fish toxicity study, to ''CR.'' To account for this change proposed test note 7 to the proposed nontarget organism table in § 158.2240 has been revised in the final rule to include an additional trigger (see § 158.2240(d) test note 7.iv). Data are required when ''the end-use antimicrobial product will be applied directly into an aquatic environment.'' EPA believes that the implications of this trigger are equivalent to the ''R'' and essentially this is a non-change. These changes are summarized here for both the aquatic areas and industrial processes and water systems testing column:

• Acute freshwater invertebrates toxicity (TEP testing): change from ''R'' to ''CR'';
• Acute freshwater fish toxicity (TEP testing): change from ''R'' to ''CR'';
• Acute estuarine and marine organisms toxicity (TEP testing): no change.

Nontarget organism toxicity testing of the TEP should be infrequently required for the antifoulant paints and coatings use pattern because for this use pattern, the TEP could be the paint. Because the testing for aquatic organisms is done in water, the test material must be soluble in water, or made soluble by addition of an appropriate solvent, if one exists, or other appropriate mechanical methods. Paint is not soluble and there may not be a way to make it soluble. Since these studies are often run in glass aquaria, the paint could coat the sides of the glass and the test animals themselves. The paint could ruin test equipment by clogging lines and injection nozzles. Therefore EPA has added a new test note 5, which is replacing proposed test note 5 to the proposed nontarget organism in § 158.2240. New test note 5 to the final nontarget organism table in § 158.2240(c) states that an applicant should request a waiver if the TEP cannot be tested.

EPA also notes that a test note specifying the number of species to be tested was omitted in the proposed rule for the TEP testing for acute freshwater fish toxicity. This test note is needed for clarity. Test note 3 to the final nontarget organism table in § 158.2240(c) has been added to the line for acute freshwater fish toxicity. Instead of ''greater than 1 ppm or 1 mg/L'' as indicated in the proposed rule, the toxicity trigger has been corrected to read ''less than or equal to 1 ppm or 1 mg/L.'' If the LC_{50} is greater than 1 ppm this means that the chemical tested was moderately to practically non-toxic on an acute basis. If the LC_{50} is less than 1 ppm this means that the chemical tested was highly to very highly toxic on an acute basis and would have a serious adverse affect(s) on the organism tested at low concentrations. For clarity, in test note 3 to the nontarget organism table, EPA has specified the appropriate trigger (less than or equal to) to indicate that testing is needed for chemicals that demonstrate high to very high toxicity on an acute basis.

D. Acute and Chronic Toxicity Data

1. *Comment.* A commenter argued that it is essential to have both acute and chronic toxicity test results for at least one freshwater invertebrate, vertebrate, and plant species, and at least one marine/estuarine invertebrate, vertebrate, and plant species.

2. *EPA's response.* EPA proposed to require acute tests for both a cold water and warm water freshwater fish, an invertebrate, and one or more aquatic plants. For marine/estuarine species, for most use patterns, EPA proposed to conditionally require acute testing with a fish and two aquatic invertebrate species, including a bivalve, when the Agency believes there is a potential for the active ingredient or a potentially toxic degradate to reach the estuarine/marine environment through transport (e.g., leaching, runoff) from the treatment site. In such a situation, chronic testing with one or more marine/estuarine species also may be required if the Agency believes that chronic exposure is likely. These studies also are required for those uses where the pesticide product is applied directly into the marine/estuarine environment.

As to chronic testing, EPA proposed to require the fish early life stage and the aquatic invertebrate life-cycle studies for the industrial processes and water systems (once-through), antifoulant coatings and paints, and aquatic areas use patterns. At that time, EPA also proposed to conditionally require the same two studies for the low environmental grouping (now called the all other use patterns category) and wood preservatives.

However, based on this and other comments, EPA has reevaluated the nontarget organism data needed for a registration decision and concluded that additional acute and chronic data are needed. Plant species encompass many different life spans. Phytoplankton reproduce quickly and have extremely short life spans. Annuals live for 1 year. Many perennials do not actually live for multiple years, but reproduce from seeds year after year. The plant species that live the longest would be woody species, such as trees. EPA does not believe that antimicrobial use patterns impact terrestrial areas such that chronic exposures occur. To EPA's knowledge, no adverse chronic effects to terrestrial plants caused by pesticides have been documented on plants. Any effect on terrestrial plant species has been categorized as an acute effect and would be covered by current testing procedures. Chronic effects of aquatic plants are covered by the aquatic testing guidelines. Algae are used as the primary test species for evaluating effects to the aquatic plants. The testing is based on growth parameters and the tests normally run for periods of time that would include several generations of the algae. The results from these algal studies, while only conducted over a few days, would be similar to those obtained from chronic testing in other species, and would be used to assess any chronic effects to aquatic plant species.

E. Avian Studies

1. *Comment.* In proposed test note 4 to the proposed nontarget organism table in § 158.2240, which triggers the avian dietary study, EPA specified a trigger of 100 mg a.i./kg (milligrams active ingredient/kilogram) for additional testing. A commenter requested information on why this trigger was selected. The commenter also claimed that EPA could use exposure tools to conduct an initial assessment based on Tier I data, and then trigger additional testing based on risk.

2. *EPA's response.* OPP has long used this value as an indication of toxicity to birds. As specified in 40 CFR 156.85(b)(3), any pesticide (including conventional pesticides) that is

intended for outdoor use with an avian acute oral LD_{50} of 100 mg a.i./kg or less requires a precautionary label statement that the pesticide is toxic to birds. EPA believes that if 100 mg a.i./kg is appropriate to trigger a precautionary label statement, then it is also appropriate to use as a trigger for testing. Therefore, if the avian oral acute toxicity study indicates an oral LD_{50} of 100 mg a.i./kg or less, then an avian dietary study is required.

In the proposed rule, for the avian dietary toxicity study, EPA proposed to require testing on two species for the aquatic areas and to conditionally require testing on one avian species for all of the other use patterns. The comments reviewed and evaluated by EPA on avian toxicity testing included the commenter's suggested data requirements table for nontarget organisms, which specified ''CR'' for all avian testing. EPA agrees with the commenter that ''CR'' is appropriate for the avian dietary toxicity and avian reproduction studies for all use patterns. This simplifies the test notes and with the appropriate triggers EPA would be able to require the needed testing.

The following changes have been made to the aquatic areas column:

- Avian dietary toxicity: change from ''R'' to ''CR'';
- Avian reproduction: change from ''R'' to ''CR''.

Test note 4 to the final nontarget organism table in § 158.2240(c) triggers the avian dietary toxicity study based on the results of the avian acute toxicity study. For the avian dietary study, testing in a second species would be triggered based on the results of the avian dietary testing in the first species. Since the second test species will be required, based on the results of the first species, proposed test note 5 is no longer needed and is being removed. Test note 6 to the final nontarget organism table in § 158.2240(c) would trigger the avian reproductive study based on one or more of four specific criteria. There were no revisions to these criteria from the proposed rule to the final rule.

F. Water Quality Criterion

1. *Comment.* A commenter argued that the registrants of any antimicrobial pesticide that has the potential to be discharged either directly or indirectly to surface water should be required to supply any additional data needed to derive a water quality criterion for the pesticide in question.

2. *EPA's response.* As discussed in the conventionals' Response to Comments Document in docket EPA–HQ–OPP–2004–0387 (p. 104), the Agency's pesticide registration process, including its data requirement regulations, adequately considers the endpoints that are protected under the Clean Water Act (CWA) as administered by the Office of Water (OW). When acceptable data are available, OPP uses these data in its risk assessment process.

The purpose of a water quality criterion under the CWA is to determine the level at which a water body may be at risk for environmental damage. The purpose of certain data requirements for pesticide registration is to allow the Agency to determine the ecological risk of using a pesticide. Thus, these program offices within EPA have similar goals. While EPA has developed guidelines for developing Water Quality Criteria (WQC), the Agency has also recognized that WQC can be developed with a more limited data set.

Pesticide registration data are valuable in assessing water quality risks. As noted in EPA's 2005 Response to Comments Document on the conventional pesticides, EPA's OW and OPP together developed aquatic life benchmarks for 71 pesticides or pesticide degradation products for States to use to establish targets for safe levels of pesticides for aquatic plants and animals. The benchmarks are derived from data submitted to EPA for pesticide registration. As of April 18, 2011, there are 242 pesticide chemicals with aquatic benchmarks on EPA's Web site (*http://www.epa.gov/oppefed1/ecorisk_ders/aquatic_life_benchmark.htm*).

G. Sediment Testing

1. *Comment.* The commenter asserted that EPA did not consider the environmental fate of a compound (such as the tendency of a chemical to absorb/desorb) when considering the need for sediment testing.

2. *EPA's response.* EPA disagrees with this comment. Test notes 17 and 18 to the final nontarget organism table in § 158.2240(c) trigger the sediment studies based on the results of the aerobic soil or aquatic metabolism studies and knowledge of the physical/chemical properties which express the environmental fate of the antimicrobial pesticide chemical. The soil partition coefficient (K_d) is used as an expression of the binding capability of the chemical to sediments. The Agency's justification for using $K_d \geq 50$ as a criterion for requiring sediment testing is that this value would capture those chemicals with about 80 percent adsorption to sediments (relative to organic carbon).

The octanol-water partition coefficient (K_{ow}) and the soil organic carbon-water partition coefficient (K_{oc}) also are used by EPA as part of its decision process. Both values are frequently more available than either the K_d or half-life values. Test note 17, the trigger for requiring an acute sediment study, considers all four of these values.

Next, as explained in test note 18, the chronic sediment study is triggered based on the results of the acute sediment study as well as a reexamination of the K_{ow}, K_{oc}, and K_d.

XII. Nontarget Plant Protection Data Requirements

The following represent the significant comments on the need for and evaluation of nontarget plant protection studies as proposed by EPA. The changes from the proposed rule to final rule are also described. A more detailed discussion can be found in the Response to Comments Document available in the docket to this rule.

A. Triggers for Higher-Tiered Plant Studies

1. *Comment.* One commenter asked EPA to explain the criteria used to trigger higher-tiered plant studies based on the results of the algal studies.

2. *EPA's response.* The criteria to trigger higher-tiered plant studies are specified in test notes 2 and 5 to the proposed nontarget plant protection table in § 158.2250. A toxicity level ($EC_{50} < 1$ ppm) indicates that the antimicrobial pesticide would have serious adverse affect(s) on algae at low concentrations. This could have serious consequences to nontarget algae species. Therefore, at this toxicity level, additional higher-tiered testing is required to further characterize the potential adverse affects to aquatic plants. EPA is retaining the toxicity trigger of <1 ppm in test note 5 to the final nontarget plant protection table in § 158.2250.

In evaluating test note 2 to the proposed nontarget plant protection table in § 158.2250, EPA has considered the commenter's suggested table for nontarget plants. For the seedling emergence study, the commenter used ''CR'' for most use patterns and suggested that the seedling emergence study should only be required ''when environmental exposure is likely to result under normal usage conditions as determined by appropriate assessment methods.'' Another comment (see response to comment 140.27 in the Response to Comments Document in the docket) advocated for the use of a Risk Quotient (RQ) approach for assessing plants.

Based on this evaluation, EPA believes using ''CR'' for the seedling

emergence study when triggered by a level of concern approach (RQ approach) would provide EPA with the required data when needed. Test note 2 to the final nontarget plant protection table in § 158.2250 now reads as: Data are required if the risk quotient from any aquatic plant growth Tier II study exceeds a level of concern for aquatic plants.

However, test note 2 also triggers the aquatic plant growth (aquatic vascular plant) study, and is still the appropriate trigger for that study. With this final rule, EPA is adding a new test note 10 to the final nontarget plant protection table in § 158.2250, which will read the same as the original, proposed test note 2 to the proposed nontarget plant protection table in proposed § 158.2250.

B. Alternative Format for Plant Protection Data Requirements Table

1. *Comment.* In the comments submitted to EPA, the commenters suggested an alternate antimicrobial plant protection data requirements table.

2. *EPA's response.* The table suggested by the commenter is not adequate to evaluate the hazards and risks to nontarget plants from antimicrobial pesticides. The suggested table did not include test guideline numbers, changed and reduced the number of use patterns, and proposed that all ecotoxicity plant studies are either not required or only conditionally required. The commenter contends that there are no circumstances where ecological effects plant data are relevant for antimicrobial pesticides, and that indoor uses should not be subject to environmental exposure or nontarget plant species risk assessments. EPA disagrees with many aspects of these comments and the suggested ecotoxicity data requirements table for plant species.

As previously discussed, in the preamble to the proposed rule (73 FR 59406–7) and in Units III. and V. of this rule, EPA disagrees that exposure for nontarget plants should be presumed to be minimal or nonexistent for antimicrobials applied indoors, or that tests are not required if the test organism is the target species for the pesticide (see ACC comment, identified in the docket by document ID No. EPA–HQ–OPP–2008–0110–0088.7, p. 12, test notes 1 and 2 to the commenter's suggested table). Moreover, there are many outdoor uses of antimicrobials that are not addressed in the commenter's suggested table. FIFRA mandates that EPA conduct a risk assessment for any uses for which exposure may occur in the various environmental compartments/media. Those risks are assessed separately for the various taxa, including plants, categories (e.g., freshwater, saltwater), and short-term (i.e., acute) and longer-term (i.e., chronic) exposures. Assessing these potential risks necessitates having an appropriate ecotoxicity data base for plant exposure and toxicity. This can only be accomplished by requiring plant studies for the initial assessment. A tiered approach cannot be driven solely by risk quotients derived from a Tier I study. The fact that an acute risk quotient for a plant species does not exceed a level of concern for acute risk does not imply that a chronic risk does not exist or that data are not needed to assess that risk. The trigger for a chronic test is more likely driven by the frequency, duration, or magnitude of the chronic exposure and the environmental properties of the pesticide. For example, plants might be subjected to repeated low-level exposure that is not acutely lethal but which may impact reproductive success and plant growth.

EPA disagrees that the test substance for plant studies (in the commenter's table) should be identified simply as the ''residue of concern (ROC).'' In its proposed nontarget plant data requirements table, EPA specified the test material (TGAI, TEP) to be used for each study. The test substance determination is made after reviewing the required environmental fate and physical/chemical properties data and any other available information (e.g., open literature, closely related chemicals) to determine the substance of concern for exposure of non-target plants and organisms. For example, if an applicant can adequately demonstrate that the TGAI dissipates so rapidly that there would be no acute or chronic exposure, TGAI testing may be waived, and instead degradate testing may be required.

The commenter also omitted all guideline numbers from its suggested data table. At this time, all data requirement tables in 40 CFR part 158 have guideline numbers since this is a method of providing information to applicants. Applicants are not required to use these guidelines, but are encouraged to use these test guidelines when developing data. Since these guidelines have been developed via a rigorous process, as discussed in the preamble to the proposed rule [73 FR 59387], ''they represent the recommended approach to developing high-quality data that should satisfy EPA's data needs for risk assessment.''

XIII. Applicator and Post-Application Exposure Data Requirements

The following represent the significant comments received on the need for and evaluation of applicator and post-application exposure studies as proposed by EPA. Changes from the proposed rule to the final rule are also described. A more detailed discussion can be found in the Response to Comments Document available in the docket to this rule.

A. Consistency With OSHA and Other Standards

1. *Comment.* A commenter asserted that EPA should be consistent with OSHA and other standards with regard to exposure limits and handling practices, and incorporate the OSHA standards into risk assessment evaluations. The commenter also asked that when EPA believes that an OSHA or American Conference of Governmental and Industrial Hygienists (ACGIH) standard is not adequately protective for an antimicrobial, that the finding should be substantiated.

2. *EPA's response.* The OSHA workplace standard is the permissible exposure limit (PEL). When developing a PEL, OSHA considers the toxicity of the chemical, often using data from the open literature as well as the feasibility that exposures could be reduced to the PEL using process modifications, engineering controls and personal protective equipment (PPE). Approximately 500 PELs have been established.

The ACGIH establishes health-based Threshold Limit Values (TLVs), which are non-governmental guidelines used by professional industrial hygienists in making decisions about safe levels of exposure to a chemical substance in the workplace. The TLVs were established for some chemicals as early as 1946 and they are updated on a regular basis as new health effects information becomes available. Like the OSHA PELs, the TLVs are based on health effects data from the open literature. However, unlike the OSHA PELs, feasibility issues are not considered in establishing TLVs. TLVs are not available for most pesticide chemicals.

However, for those pesticide chemicals with both TLVs and RfCs (Reference Concentrations are established by OPP based on studies submitted by the registrants), the RfCs are often lower than the TLVs. There could be several reasons for such differences. The data used by OPP is submitted by the pesticide registrants and the toxicity data base is composed of animal studies. So, uncertainty

factors are used to derive the RfCs (exposure limits). Instead of animal studies, ACGIH prefers to rely on epidemiology studies/case reports of human, particularly worker, exposures from the literature and on professional judgment.

For example, ACGIH and OPP established different inhalation limits for formaldehyde based on slightly different interpretations of the same literature studies. The TLV for formaldehyde is 300 ppb and the OPP ''RfC'' for occupational uses is 100 ppb. Although the TLV is greater than the ''RfC,'' ACGIH does acknowledge in their TLV documentation that irritation can occur in some workers at levels of 100 to 300 ppb.

EPA believes that an existing OSHA or ACGIH standard should be considered as part of EPA's hazard evaluation. However, before using an OSHA or ACGIH standard, EPA would review the standard and the health effects (toxicology) documents supporting the standard's development to determine if EPA believes that the standard provides adequate protection. EPA agrees with the commenter that EPA's evaluation of an existing OSHA or ACGIH standard should be part of its hazard evaluation documentation.

In its proposed rule, EPA proposed in the applicator exposure table (40 CFR 158.2260(a)(1)) and the post-application exposure table (40 CFR 158.2270(a)(1)) to use established workplace standards, such as OSHA's. The proposed language was:

> If EPA determines that industrial standards, such as the workplace standards set by the Occupational Safety and Health Administration, provide adequate protection for a particular pesticide or a particular use pattern, applicator exposure data may not be required for that pesticide or the use pattern. Applicants should consult with the Agency on appropriate testing before the initiation of studies.

In addressing this comment, EPA realized that this proposed language is misplaced and also needs some textual modification. As discussed previously, an OSHA PEL or ACGIH TLV standard is part of hazard evaluation. If the PEL or TLV is determined to be adequate to fulfill EPA's selection of a toxicity endpoint, then the types and number of toxicity studies that may be required is impacted, not the need for exposure data. Therefore, EPA has removed the language originally proposed for § 158.2260(a)(1) and § 158.2270(a)(1) concerning use of OSHA standards. With modifications, the language appears in the final toxicity rule in § 158.2230(e).

B. Poisoning Incident Data

1. *Comment.* ''Poisoning incident data'' should not be incorporated into this regulation unless the EPA can provide criteria to trigger the need for exposure data based on poisoning incidents. Regulating based upon anecdotal reports of ''poisoning'' is not appropriate.

2. *EPA's response.* Both proposed § 158.2260(b) and § 158.2270(b) contained the following trigger for requiring exposure data: ''Scientifically sound epidemiological or poisoning incident data indicate that adverse health effects may have resulted from handling of the pesticide.'' EPA understands that anecdotal reports may or may not indicate a cause-effect relationship, i.e., that adverse health effects may or may not have resulted from exposure to the pesticide. EPA agrees that anecdotal reports may not substantiate a clear dose response relationship of ''poisoning,'' and therefore, when not substantiated, are not appropriate for regulatory endpoints. In-depth information on the dose response is the critical information needed for regulatory endpoints, and poisoning incident data rarely include this information. However, EPA's intention was to use scientifically credible information as a trigger for requiring exposure data. Based on this comment, EPA has revised the toxicity triggers in § 158.2260 and § 158.2270 to clarify that poisoning incident data must have a clear cause-effect relationship to indicate that adverse health effects have resulted from exposure to the pesticide.

C. Use of Existing Post-Application Exposure Data

1. *Comment.* A commenter argued that there is a significant amount of post-application exposure data available that should be considered/used before requiring data under FIFRA.

2. *EPA's response.* EPA acknowledges that there are existing exposure data either in the literature, or via other governmental organizations such as OSHA, or academia, etc. When available and appropriate, EPA uses such exposure data and/or information in its risk assessments. For example, the risk assessments for both chlorine dioxide and ethylene oxide relied heavily on the workplace air concentration monitoring data available in OSHA's Chemical Exposure Health Database (CEHD), formerly known as, Integrated Management Information System (IMIS). To access CEHD, users navigate on the OSHA homepage (*http://osha.gov/*) to Chemical Exposure Health Data under the Data and Statistics section towards the bottom right of the page. Users can search CEHD by Establishment Name, State, Zip Code, Year Range, Standard Industrial Classification (SIC), North American Industrial Classification System Code (NAICS), Chemical Abstracts Service Number (CAS), Chemical Name, or Result Range.

Applicants who are aware of existing data that could fulfill a data requirement should submit the data to EPA. EPA will consider the appropriateness and robustness of the data, and, if appropriate, will use the data in the Agency's risk assessment.

D. Soil Residue and Indoor Surface Residue Dissipation Studies

1. *Comment.* A commenter claimed that there is little justification for requiring the soil residue dissipation and indoor surface residue dissipation studies.

2. *EPA's response.* In the proposed rule, EPA conditionally required the soil residue dissipation study for both occupational and residential scenarios. EPA agrees that the likelihood of requiring soil residue dissipation data is low for the majority of antimicrobial use patterns. The low likelihood is reflected in the ''CR'' designation in the proposed post-application exposure data requirements table for the soil residue dissipation study for both occupational and residential use patterns. No changes are needed.

In the proposed rule, EPA required the indoor surface residue dissipation study for both occupational and residential scenarios. However, the likelihood of requiring indoor surface residue dissipation data is high for residential products such as antimicrobial-treated clothing and plastic consumer items/toys, as well as direct applications such as carpet shampoos, laundry detergents, and floor cleaners that are antimicrobial products. Therefore, the indoor surface residue dissipation study for the residential use sites will remain ''R'' as proposed.

However, EPA has reevaluated the ''R'' proposed for occupational use sites. When compared to residential use sites, occupational use sites are less likely to result in the need for indoor surface residue dissipation data. Therefore, the data requirement for indoor surface residue data has been revised from ''R'' to ''CR'' for occupational uses.

In most manufacturing settings, there is less contact with surfaces than in most residential scenarios. For example, under most circumstances workers do not crawl around the floors of manufacturing plants. The need for indoor surface residue dissipation data

for workers is limited by the residue distribution where contact may occur. EPA now agrees that the occupational use sites are less likely to result in the need for indoor surface residue dissipation data, and therefore, the ''R'' has been revised to ''CR.''

E. Non-Dietary Ingestion Study

1. *Comment.* A commenter asserted that the proposed requirement for non-dietary ingestion is impractical and unnecessary, and, in fact, could be replaced by modeling.

2. *EPA's response.* EPA agrees that the non-dietary ingestion study is impractical, as a stand-alone direct measurement study. Non-dietary ingestion exposure (i.e., incidental oral ingestion by children) is of potential concern for treated articles or surfaces that may be accessed by children. For example, uses such as carpet shampoo, hardwood floor treatments, pressure-treated wood, and impregnated materials (including but not limited to plastic toys or treated clothing) are assessed for non-dietary exposures when toxicity criteria are triggered. In all of these instances, non-dietary ingestion exposures are estimated using residue data from the treated surface combined with activity factors for children's behaviors (e.g., frequency of hand-to-mouth contact). Often, EPA models this route and pathway of exposure using inputs from the available and reliable published research. If EPA were to require data to estimate this exposure pathway, EPA would require surface residue data, rather than the actual monitoring of children or having individual registrants collecting data on frequency of hand-to-mouth activities, as these are not chemical-specific. Given the unlikelihood of requiring non-dietary ingestion exposure studies, EPA has determined to not finalize this proposed data requirement and its accompanying test note 12 in the final post-application exposure table in § 158.2270(e).

XIV. Environmental Fate Data Requirements

The following represent the significant comments received on the need for and evaluation of environmental fate studies as proposed by EPA. Changes from the proposed rule to the final rule are also described. A more detailed discussion can be found in the Response to Comments Document available in the docket to this rule.

A. Need for Environmental Fate Data for Indoor Uses

1. *Comment.* Several commenters argued that the proposed environmental fate data requirements for indoor uses of antimicrobials should not exceed those in part 158 for conventional pesticide chemicals, since antimicrobials are not directly broadcast into the environment.

2. *EPA's response.* As explained in the proposed rule, there is now a greater concern regarding indoor uses of antimicrobials because those antimicrobial uses can lead to environmental exposure when they go down the drain. The rationale for requiring environmental fate data for antimicrobials mirrors that of Unit XI.A. for requiring nontarget organism data for antimicrobials.

There are many uses for which a high potential for exposure exists, and these uses may require a more extensive environmental fate data set that could also include aerobic and anaerobic metabolism studies. However, such uses will typically require a much reduced first tier data set with additional testing triggered if the results of the required data indicate a potential risk that needs further characterization.

B. Transformation Products

1. *Comment.* A commenter argued that the Agency has not clearly stated when environmental fate data on the transformation products would be required. Additionally, the commenter also wanted to understand the data that would be required if the substance degrades quickly?

2. *EPA's response.* For environmental fate data, the Agency evaluates transformation products on a case-by-case basis, using several sources of information. First, the transformation products need to be identified. While product chemistry data can provide some information on degradates, environmental fate data provide data specific to a particular environmental compartment. Environmental fate studies provide information on the stability and persistence of the active ingredient and its degradation products in the various environmental media. For example, in the hydrolysis study, a half-life >30 days indicates that the substance is stable to hydrolytic processes, i.e., the substance did not degrade. Similar determinations are made based on the results of the photodegradation in soil and water studies, and the aerobic and anaerobic metabolism in soil and water studies after review of the required fate data. Monitoring and incident data, if available, also may indicate stability and persistence. There could also be environmental fate data conducted on a related chemical or information from the open literature. This analysis is critical to determining not only the need for environmental fate data for transformation products, but also is the first step for determining the need for nontarget organism or nontarget plant data for transformation products.

EPA proposed criteria to require testing of transformation/degradation products or leachate residues in proposed § 158.2280(a)(2) and (3). To respond to this comment, EPA also considered a similar comment on transformation/degradation products or leachate residues for nontarget plant and organism testing (see Unit XI.B.). In response to these comments, EPA determined to clarify and revise the criteria for testing of transformation/degradation products and leachate residues for nontarget organisms in § 158.2240(a)(3), for environmental fate in § 158.2280(a)(2), and for nontarget plant protection in § 158.2250(b).

EPA would use these criteria to determine if environmental fate data on the transformation/degradation products or leachate residues are required. Therefore, if the environmental fate studies on the parent indicate the transformation product(s) is, for example, more persistent in soils, then the same environmental fate data required for the parent are required for the transformation product(s). If concerns are identified, then higher-tiered environmental fate and/or ecological effects data on the transformation/degradation product(s) would be required.

It should be noted that the criteria for determining whether to assess risks from a chemical substance and/or its degradation products when conducting a down-the-drain analysis are different from those discussed previously. Those criteria are discussed in response to comment 130.4 in the Response to Comments Document in the docket.

C. Photodegradation in Soil Study

1. *Comment.* A commenter claimed that EPA has not sufficiently explained why a photodegradation in soil study would be required if a substance hydrolyzes and its behavior is known from its soil profile.

2. *EPA's response.* EPA proposed to require the photodegradation in soil study for only one use pattern: Wood preservatives. Wood products that have been treated with wood preservatives are often in contact with soil, and therefore it is possible for the wood preservative chemical, as well as its transformation and degradation products, to leach out from the treated wood product. To understand the fate of wood preservative chemicals in soil, first requires an understanding of the soils properties. Soil profiles are

descriptions of soil properties, both physical and chemical. Examples of physical characteristics would include: color, bulk density, and texture. Examples of chemical characteristics would include: pH of the soil, organic matter content, and Cation Exchange Capacity (CEC). Depending on the soil profile, an antimicrobial pesticide can undergo chemical and/or biochemical (biodegradation) processes. For example, if the pH of the soil is less than 7, the antimicrobial can undergo hydrolysis and become nonpersistent, or if the pH of the soil is basic, the antimicrobial could remain stable and become persistent. If the organic carbon content of a soil is high, then the soil has a high microbial population which facilitates the biodegradation process. Hence the nature of a soil (soil profile) is an important indicator of how a pesticide may behave in a soil.

Many applicants are well aware of soil profiles, since EPA asks for the soil profile to be submitted along with the results of the studies in soils. A number of soil profile data bases are available. Two of the data bases used by OPP are one from the United States Department of Agriculture (USDA) and one called CLARION.

In this final rule, EPA has retained the requirement for a photodegradation in soil study for the wood preservatives use pattern. The photodegradation in soil study is required for all wood preservatives, except for two circumstances. First, if the antimicrobial is an inorganic substance or a metal salt, then a photodegradation study does not provide applicable information for inorganics and metal salts that do not degrade (chemically or biochemically). Second, if data from standardized soil profiles show that the chemical is likely to readily degrade microbially or undergo redox reactions (degrade chemically) to such a degree that there is no formation of degradation/transformation/leachate products of concern (as defined in § 158.2280(a)(2)), then the photodegradation in soils study would not be needed. EPA has revised the proposed test note 10 to the environmental fate table, so that test note 10 to the final environmental fate table in § 158.2280(c) explains the conditions for not requiring the photodegradation in soil study.

D. Aquatic Sediment Study

1. *Comment.* A commenter claimed that EPA is unclear about the triggers that would lead to the requirement for an aquatic sediment study, and how down-the-drain modeling could affect the need for this study.

2. *EPA's response.* Test notes 5 and 13 to the proposed environmental fate table in § 158.2280 trigger the aquatic sediment study for all use patterns except the aquatic areas use pattern. EPA has reevaluated the need for the aquatic sediment study and the appropriate triggers. EPA agrees that having two triggers, both of which use a weight-of-evidence evaluation process, is confusing, and believes that one trigger (proposed test note 13) would be sufficient for triggering the aquatic sediment study. In this final rule, EPA is removing test note 5 from the test note column for the aquatic sediment study data requirement. Based on this reevaluation, EPA also believes that the aquatic sediment study should be required for the antifoulant coatings and paints use pattern since an antifoulant use would meet the criteria of the trigger in test note 13, which is: ''* * * data are required based on the potential for aquatic exposure and if the weight-of-evidence indicates that the active ingredient or principal transformation products are likely to have the potential for persistence, mobility, nontarget aquatic toxicity, or bioaccumulation.'' Antifoulants are released/applied directly to the aquatic environment. These products are often manufactured to be persistent, and because of the continuous release process, some of the active ingredient is likely to be transferred to the bottom of the water column and then be adsorbed to the sediment. This is likely to result in adverse effects on nontarget benthic organisms. Since this meets the triggers for requiring the study, in this final rule EPA is changing the ''CR'' for the aquatic sediment study for the antifoulant coatings and paints use pattern to ''R.''

The aquatic sediment study provides information about the degradation/dissipation processes under field conditions. The results of down-the-drain modeling are unlikely to provide appropriate information to determine the need for the aquatic sediment study. The current version of the down-the-drain model estimates concentrations of chemical substances in the water column downstream of wastewater treatment facilities, but does not estimate concentrations in the sediment.

E. Monitoring of Representative U.S. Waters Study

1. *Comment*. The commenter noted that there is no guidance on how to conduct a ''monitoring of representative U.S. waters'' study, and that EPA has not provided the criteria for triggering a ''monitoring of representative U.S. waters'' study.

2. *EPA's response.* The commenter is correct. EPA does not have a guideline for conducting this study. For all pesticides, such monitoring (studies) of representative U.S. waters is a very rare occurrence. If EPA were to require such a monitoring study, protocols would have to be developed to specify a great deal of information:

- At which locations would the monitoring occur, and how often would the monitoring occur?
- Is the sampling for ground water, surface water, or the estuarine/marine environment?
- Which chemical substances would be monitored? Is just the antimicrobial (parent) to be analyzed, or would the transformation/degradation products also be analyzed?

Such a protocol would be specific to a particular pesticide, where that pesticide is used, and where the pesticide has been detected, and could not necessarily be used for a different pesticide.

For the monitoring of representative U.S. waters data requirement, the term ''residue of concern'' (ROC) is currently specified in the environmental fate data requirements table in the test substance to support column. Since the ROC would be determined during protocol development, EPA is adding this information as part of a new test note 17 to the final environmental fate table in § 158.2280.

As stated in the preamble to the proposed rule, a WOE approach would be used to determine if a monitoring of representative U.S. waters study should be required. The preamble to the proposed rule discusses this aspect in more detail (73 FR 59413). EPA expects this study to be rarely required.

F. American Wood Protection Association (AWPA) and American Society for Testing and Materials (ASTM) Methods

1. *Comment.* A commenter argued that AWPA method E11–97 or E20–04, and ASTM Method D5108–90 ''are of limited or no relevance to estimating environmental exposures'' for wood preservatives, or antifoulants, respectively. According to the commenter, the results of the ASTM method are not suitable for ''estimating release rates for regulation purposes.'' The commenter believes that both methods ''overestimate leach rates and are not intended for use in risk assessments.'' The commenter also provided information to indicate that ASTM Method D5108–90 has been replaced by ASTM D6442–06.

2. *EPA's response.* Test note 15 to the proposed environmental fate table in

§ 158.2280 triggers the special leaching data requirement for the wood preservative use pattern. EPA's intent in specifying that it would accept an ASTM or AWPA method was to allow applicants to use these readily available protocols. However, as noted in the proposed test note, protocol review was still required for some of these methods. Since the commenters believe that these AWPA methods are inappropriate, but have not offered alternative methods, test note 15 to the final environmental fate table in § 158.2280(c) is revised to remove the AWPA methods. Test note 12 to the final environmental fate table in § 158.2280(c) is added to require protocol review.

Test note 16 to the proposed environmental fate table in § 158.2280 triggers the special leaching data requirement for the antifoulant coatings and paints. Since the commenter indicated that the ASTM method has been replaced, EPA believes that specifying an ASTM method number in regulatory text may provide insufficient clarity, at some point in the future. Therefore, test note 16 to the final environmental fate table in § 158.2280 is revised to remove the ASTM methods. Test note 12 to the final environmental fate table in § 158.2280(c) is added to require protocol review.

XV. Down-the-Drain Analysis

The following represent the significant comments received on the need for and performance of a down-the-drain analysis as proposed by EPA. Changes from the proposed rule to the final rule are also described. A more detailed discussion can be found in the Response to Comments Document available in the docket to this rule.

A. Changes to Down-the-Drain Analysis Based on Comments Received

1. *Comment.* Some commenters expressed concern regarding EPA's proposal to exclude antifoulants and wood preservatives from testing designed to protect POTWs and the aquatic environment. These commenters contend that these compounds may reach POTWs through sources such as hull blast water, landfill leachate, and centralized waste treatment facilities. They think EPA should revisit this assumption to verify its accuracy.

2. *EPA's response.* Based on this comment, EPA did reevaluate its original determination to exclude antifoulant coating and paints, wood preservatives, and aquatic areas from down-the-drain analysis. EPA still believes that it is appropriate to exclude aquatic areas from a down-the-drain analysis. As discussed in the preamble to the proposed rule (73 FR 59390) aquatic areas include lakes, ponds, streams, drainage ditches, and other bodies of water. These would not be expected to result in down-the-drain releases and are therefore unlikely to be discharged to a WWTP.

Based on its reevaluation, EPA believes that a down-the-drain analysis is needed for the wood preservative, and antifoulant paints and coatings use patterns, as well as the all other use patterns category. There are a number of sources of indirect releases of antifoulants and wood preservatives to surface water via WWTPs. The Emission Scenario Document (ESD) for Wood Preservatives, which is part of the OECD Series on Emission Scenario Documents, documents numerous sources of environmental releases directly to surface water. The ESD also describes various types of wood preservative facilities where there may be environmental releases to the facility drain that subsequently drains to a WWTP. Some of the types of wood preservative facilities identified in the OECD ESD for wood preservatives include automated spraying plants, dipping/immersion plants, and plants that employ vacuum-pressure and double vacuum processes. According to this OECD ESD for wood preservatives, it is also possible for releases to sewage treatment plants to occur from some treated wood products, such as noise barriers.

According to the OECD ESD for Antifouling Products, in addition to the numerous sources of direct environmental releases to surface water resulting from the use of antifoulant paints and coatings, there is the potential for antifoulants to enter sewage treatment plants as a result of application and removal of antifoulant paints at boatyards and marinas.

Thus, OPP's Antimicrobial Division (AD) will perform a down-the-drain assessment for every product with an applicable use or exposure scenario that has the potential for waters containing antimicrobials to reach a WWTP. To perform this assessment, the Agency is requiring data on the biodegradation of an antimicrobial pesticide and its potential toxicity to WWTP microorganisms in an activated sludge basin. For some antimicrobial pesticides, the Agency will also require the activated sludge sorption isotherm test to determine removal from wastewater via partitioning to activated sludge. For additional information on the changes made to the proposed environmental fate data requirements table see response to comment 134.1 in the Response to Comments Document in the docket.

B. Use of E–FAST Model

1. *Comment.* According to one commenter, EPA staff indicated at the part 158, subpart W Antimicrobials Data Requirements Workshop held on November 6, 2008 that the E–FAST model may have been based on municipal WWTPs that received only ''residential'' discharges. The commenter suggested that is very unlikely and stated that according to the E–FAST manual, the model was based on data from actual U.S. municipal WWTPs. Nearly every municipal WWTP receives discharges from many types of non-residential sources, like commercial facilities, medical facilities, institutions, and cooling water systems (which are common in commercial buildings). Even in smaller communities, POTWs receive wastewater from residential and commercial (e.g., schools, stores, restaurants, hotels/motels, and/or medical facilities) sources. Most municipal WWTPs also receive both process and non-process discharges from industrial facilities. Some commenters contend that the E–FAST model is applicable as a screening-level model for all antimicrobial use patterns with discharges that are typically rinsed down the drain including agricultural premises and equipment, food handling/storage establishments, residential and public access premises, medical premises and equipment, industrial processes and water systems, swimming pools, and others.

2. *EPA's response.* The E–FAST documentation manual indicates that the down-the-drain module was developed as a screening-level model for estimating concentrations of chemicals in surface water that may result from the disposal of consumer products into household wastewater. The model developers have confirmed, however, that the data base of WWTPs that is accessed by this module consists of domestic WWTPs that receive wastewaters predominantly from residential, commercial, and institutional sources, and not solely from residential sources. In modeling releases of antimicrobial pesticides to environmental media, the appropriate data inputs, methods, and tools are dependent upon the source of the environmental releases. To assess exposures and risks to releases of antimicrobial pesticides to surface water from residential, commercial, and institutional sources, the down-the-drain module of E–FAST is the most appropriate tool.

To assess exposures and risks to antimicrobial pesticides from manufacturing, processing, and industrial use facilities, the general population and ecological exposures from the industrial releases module of E–FAST is the most appropriate tool. The decision to use the general population and ecological exposures from the industrial releases module is made on a case-by-case basis considering the availability of data required as inputs to the module, and the potential for significant exposure. For example, a low volume use may not require use of this module.

EPA agrees that the E–FAST model is applicable as a screening-level model for all antimicrobial use patterns with discharges that are typically rinsed down the drain, including agricultural premises and equipment, food handling/storage establishments, residential and public access premises, medical premises and equipment, industrial processes and water systems, swimming pools, and others.

C. Exceedance Levels

1. *Comment.* Some commenters questioned the justification for the following exceedance levels that were used by EPA to evaluate potential risks to aquatic organisms:

i. Potential risks from effects to aquatic invertebrates and fish: Exceedance of the chronic concentration of concern (COC) for 20 or more days triggers a potential for concern;

ii. Potential risks from effects to aquatic invertebrates and fish: Exceedance of the acute COC for 4 or more days triggers a potential for concern; and

iii. Potential risks from effects to algae: Exceedance of the COC for algae for 4 days or less may trigger a concern and is evaluated on a case-by-case basis.

2. *EPA's response.* Exceedance levels and corresponding number of days of exceedance that trigger potential for concern are those cited in EPA/OPPTS/OPPT's ''Interpretive Assistance for Sustainable Futures Summary Assessment'', last updated August, 2011. The justification that the potential for chronic risk to aquatic organisms may exist if the predicted environmental concentration (PEC) exceeds the chronic COC and the exceedance occurs for 20 days or more per year is documented on page 11:

> The potential for chronic risk to aquatic organisms may exist ONLY if the PEC exceeds the chronic COC for 20 days or more per year. If exposure occurs for 20 days of more per year, the concentration of the chemical in surface water may reach levels associated with chronic effects (Lynch et al., 1994). The 20-day criterion is derived from partial life-cycle tests (Daphnid chronic and fish early life-stage tests) that typically range from 21 to 29 days in duration. Low concentration for chronic risk exists if the COC is exceeded on fewer than 20 days per year.

The justification for the potential for acute risks to aquatic organisms appears on page 12:

> The potential for acute risk to aquatic organisms exists if the predicted environmental concentration (PEC) is greater than the acute concentration of concern (COC).
>
> If Acute COC > PEC: Low concern for risk
>
> If Acute COC < PEC: Potential for risk

EPA notes that risk is influenced by both the duration of exposure and the likelihood of that exposure occurring. Often mathematical models are used to estimate exposures and risks. There are two types of models: Deterministic or probabilistic. Probabilistic modeling is a technique that utilizes the entire range of input data to develop a probability distribution of risk or exposure rather than a single point value. The analysis identifies the probability that the exposure exceeds the COC and for what timeframe. Deterministic modeling is based on select input data that result in a single point estimate. The estimate either exceeds or does not exceed the COC. Models such as E–FAST have the capability of providing either deterministic or probabilistic results. Consequently, criteria for determining whether or not testing on aquatic organisms is required need to take into account the possibility that the estimated exposure could be modeled using either deterministic or probabilistic modeling. Therefore, two test notes to the final nontarget organism table in § 158.2240 have been revised to include a probabilistic trigger for down-the-drain analyses, while retaining the existing deterministic trigger for releases of antimicrobials that are expected to enter WWTPs. Test note 7 to the final nontarget organism table in § 158.2240(c) triggers the acute freshwater invertebrate toxicity study (TEP testing) and the acute freshwater fish toxicity study (TEP testing). Test note 12 to the final nontarget organism table in § 158.2240(c) triggers the fish life-cycle study.

D. Evaluation of Discharges to Still Water and to Salt Water

1. *Comment.* During the Antimicrobial Data Requirements Workshop held on November 6, 2008, EPA staff indicated that evaluation of discharges to still water and to salt water would be challenging. The commenter argued that the E–FAST model manual suggests that these discharges can be readily evaluated with appropriate input data and elimination of the PDM (Probabilistic Dilution Model) option.

2. *EPA's response.* EPA believes that the commenter misunderstood the context of the Information provided by EPA staff both in the proposed rule and at the presentation on November 6, 2008. E–FAST has two modules for estimating releases to surface water: The down-the-drain module, and the general population and ecological exposure from industrial releases module.

When the down-the-drain module of E–FAST is run without the PDM option, the results are limited to estimates of concentrations in surface water downstream of domestic wastewater treatment facilities. The down-the-drain module has no option for estimating concentrations in non-flowing waterbodies such as lakes, bays, estuaries, and oceans. The discussion at the November 6, 2008, Workshop focused solely on the down-the-drain module.

E–FAST, however, has the capability for evaluating discharges to still water and to salt water from discharges to WWTPs that receive manufacturing, processing, and industrial use releases, but not from discharges to surface water via domestic WWTPs. The general population and ecological exposure from industrial releases module is designed to estimate releases to air, water, and land from manufacturing, processing, and industrial use of chemical substances. The data base for estimating releases to WWTPs that primarily receive wastewater from manufacturing, processing, and industrial uses requires estimates of releases to environmental media from models such as ChemSTEER (Chemical Screening Tool for Exposures and Environmental Releases), a model developed by EPA's OPPT or from data and calculations included in standard scenarios, also developed by OPPT (*www.epa.gov/oppt/exposure/pubs/chemsteerdl.htm*). The general population and ecological exposure from industrial releases module includes an option for estimating concentrations in lakes, bays, estuaries, and oceans.

E. Parameters for Down-the-Drain Analysis

1. *Comment.* Several commenter's argued that EPA's approach for down-the-drain chemicals separates the exposure and the effects of the assessment and subjects chemicals to similar testing requirements regardless of the mass of chemicals disposed of in

the environment. According to these commenters, the fact that EPA does not guide testing by the extent of environmental exposure is wasteful for ingredients which will reach the environment at low levels. Even for chemicals which are used at greater volume, the commenters claimed that there is no proof that EPA's program will achieve its goal without being wasteful and some commenters believe that EPA's approach will likely result in significant unwarranted costs in animals, time, and dollars. The commenters asserted that this will result in unnecessary loss of animals, increased costs to the consumer and will negatively affect product innovation as new product development will be slowed due to the extra regulatory burden. The benefit to the environment of the EPA approach, according to the commenters, is likely to be small and not commensurate with its costs.

2. *EPA's response.* EPA disagrees with this comment. Three key input parameters for the down-the-drain model are:

i. Percent removal of antimicrobial pesticide during wastewater treatment;

ii. Concentrations of concern for antimicrobial pesticides based on acute and chronic end-points for freshwater fish, freshwater invertebrates, and freshwater plants; and

iii. Wastewater treatment plant influent volume of antimicrobial pesticide.

As demonstrated in the sensitivity analysis of the down-the-drain model in the document, ''Four Case Studies of Antimicrobial Pesticides in the Down-the-Drain Screening Model, Using the Proposed Approach for a Screening-Level Environmental Fate Assessment'' (identified in the docket by document ID number EPA–HQ–OPP–2008–0110–0044), the amount of chemical disposed in the environment strongly influences the results of the down-the-drain model. It is possible that if the amount of chemical disposed is small (i.e., WWTP influent volume is low and/or high percent removal during wastewater treatment), the predicted surface water concentration of the antimicrobial, even for a chemical of high toxicity, would not exceed the Agency's level of concern. Under such circumstances, higher-tier testing (environmental fate, ecotoxicity, and plant protection) is unlikely to be triggered. Since higher-tier testing is triggered only if the down-the-drain model indicates that the predicted concentration of the antimicrobial may adversely affect aquatic organisms this reduces the number of tests required, and therefore the animals, time, and dollars.

EPA also notes that two of the three key input parameters needed to run the down-the-drain model, percent removal during wastewater treatment and wastewater treatment plant influent volume do not involve animal testing and would not lead to loss of animals. Fate tests required to determine removal during wastewater treatment via biodegradation and adsorption are inexpensive. No costs are associated with WWTP influent volume.

F. Acute and Chronic Toxicity Endpoints

1. *Comment.* At the Antimicrobial Data Requirements Workshop held on November 6, 2008, EPA staff indicated that chronic aquatic toxicity endpoints might not be used to evaluate antimicrobial discharges from municipal WWTPs. A commenter argued that since EPA/OW requires municipal WWTPs to conduct both acute and chronic toxicity tests regularly as conditions of CWA-regulated National Pollution Discharge Elimination System (NPDES) permits, both acute and chronic endpoints should be evaluated by EPA/OPP to ensure that antimicrobial discharges will not cause toxicity in municipal WWTP effluent.

2. *EPA's response.* To assess whether the proposed screening level assessment and tiered system of data requirements provides the data needed to assess exposure and risk of antimicrobial pesticides released to the environment via down-the-drain use patterns, the Agency conducted four case studies (73 FR 59408–9). Based on this comment, EPA has reevaluated the approach used for the case studies, in which the higher-tiered data was triggered based on the results of the available data. To ensure that antimicrobial discharges will not cause toxicity to aquatic organisms downstream of WWTP effluents requires an evaluation of both acute and chronic toxicity endpoints. This means that the chronic ecotoxicity data needs to be submitted at the same time as the acute ecotoxicity data, so both types of studies are available for EPA to use for the ecological risk assessment. Also see Units XV.A. and B.

Consequently, in the final nontarget organism table in § 158.2240(c), the table descriptors for the fish early-life stage and aquatic invertebrate life-cycle tests have been changed from ''CR'' to ''R'' for the wood preservatives use pattern and the all other use patterns category. Test note 10 to the final nontarget organism table in § 158.2240(c) has been modified to remove the trigger since it is no longer needed.

XVI. Residue Chemistry Data Requirements

The following represent the significant comments received on the need for and evaluation of residue chemistry studies as proposed by EPA. Changes from the proposed rule to the final rule are also described. A more detailed discussion can be found in the Response to Comments Document available in the docket to this rule.

A. Scope of the Residue Chemistry Data Requirements

1. *Comment.* Several commenters found the scope of coverage of the residue chemistry data requirements in § 158.2290(b) to be vague and confusing. Further, the ACC Biocides Panel asserted that this section required data for uses for which a FFDCA section 408 tolerance is not required and over which, therefore, EPA allegedly has no jurisdiction.

2. *EPA's response.* EPA is clarifying § 158.2290(b) which pertains to the scope of the residue chemistry data requirements. That section can be read as limiting the residue chemistry data requirements to pesticide products requiring a tolerance or tolerance exemption. This apparent limitation is inconsistent with both the preamble's general description of the scope of subpart W and the preamble's description of the scope of the residue chemisty data requirements section, and is internally inconsistent with the terms of § 158.2290(b). Various commentators noted the lack of clarity in this portion of the rule.

The preamble's general discussion of the scope of subpart W made clear that this subpart was not limited to ''antimicrobial pesticides'' as defined by FIFRA section 2(mm)—which excluded antimicrobial pesticide uses subject to either FFDCA section 408 or section 409—but extended to among other things, ''[p]esticide products for antimicrobial use in/on food'' (73 FR 59385). In no way, however, did this discussion suggest or imply that the subpart is limited to antimicrobial uses requiring FFDCA section 408 tolerances or exemptions from tolerances. To the contrary, the preamble's discussion of toxicity data requirements expressly notes that data are needed under subpart W to assess dietary risk whether or not a section 408 tolerance is required. The preamble specifically states that, although certain antimicrobial food uses are regulated under the FFDCA by FDA under section 409 and not section 408, EPA still needs

data on these uses to assess dietary risk to fulfill its statutory obligations under FIFRA section 2(bb)(2), which establishes the FFDCA section 408 safety standard as a component of the FIFRA standard for registration/cancellation for FIFRA pesticide uses that result in residues on food (73 FR 59394). Further, the preamble's discussion of residue chemistry data requirements states that these data are needed for ''direct and indirect food uses'' including application to ''food or water'' both to assess risk and for tolerance-setting purposes (73 FR 59401: ''In addition to dietary risk assessments, residue chemistry data are used to establish pesticide tolerance. . . .''). Finally, both the preamble's discussion of residue data requirements and the relevant rule text mention antimicrobial uses that would be excluded by a limitation of the rule to antimicrobial uses requiring tolerances. For example, both the preamble and rule text refer to ''fruit and vegetable rinses,'' antimicrobials ''incorporated into a material that may contact food or feed,'' and ''[a]quatic uses that have the potential to result in residues in potable water'' and the fact that all of these uses may not need section 408 tolerances (73 FR 59401 and 59444).

Accordingly, EPA is revising § 158.2290(b) to make clear it is not limited to antimicrobial uses which need FFDCA section 408 tolerances. With some modifications, EPA is retaining in § 158.2290(b) a non-exclusive list identifying examples of antimicrobial products covered by this section. The revision to the introductory text of § 158.2290(b)(1) makes clear that the residue data requirements apply to antimicrobial products that may result in residues in food or water whether or not a FFDCA section 408 tolerance is needed.

The first item in the list of covered uses now reads ''Products that require a tolerance, tolerance exemption, or food additive regulation or clearance.'' The insertion of the reference to food additive regulations and clearances is consistent with the rule's scope which is not limited to pesticide uses regulated under FFDCA section 408. Additionally, each of the subparagraphs listing examples of covered uses has been revised to refer to ''products'' rather than ''uses'' for consistency and clarity. Although the subparagraphs are overlapping (i.e., a product may fall in more than one paragraph), the revised subsection now clarifies the overall scope of the section. These revisions make § 158.2290(b) consistent with the scope of the rule described in the preamble and the scope of the toxicology data requirements.

Not only are these changes consistent with the scope of the rule as discussed in the preamble (i.e., data requirements are not limited to uses needing section 408 tolerances) but the revised language's focus on whether use of a pesticide may result in residues in or on food follows directly from the intent of the residue chemistry requirements as discussed in the preamble. There, EPA explained that the proposed requirements will provide information ''to better estimate human dietary exposure to antimicrobial residues in or on food or feed,'' ''to determine the composition of the pesticide residue and how much of the residue is present in food or animal feed,'' and to ''measure how much of the residue of concern is present in food, feed, and water'' (73 FR 59401). Further, the revised language is consistent with the scope of FFDCA section 408 (applies to ''pesticide chemical residue[s] in or on food'') and FIFRA (requires consideration of ''residues that result from the use of a pesticide in or on food''). It also follows directly from the existing data requirements applying to antimicrobials in part 161. Those regulations provide that ''Residue Chemistry Data are used by the Agency to estimate the exposure of the general population to pesticide residues in food and for setting and enforcing tolerances for pesticide residues in food or feed.'' 40 CFR 161.202(c)(1); *see also* 40 CFR 161.202(c)(2) (''results of tests on the amount of residues remaining on or in the treated food or feed are needed to support a finding as to the magnitude and identity of residues which result in food or animal feed as a consequence of a proposed pesticide usage''); 40 CFR 161.240(b)(14) (Residue data on indoor use of pesticide ''if such a use could result in residues in food or feed''). Finally, the revised language also tracks EPA's requirements for residue chemistry data under the current data requirements for conventional pesticides in 40 CFR part 158, subpart O. In the preamble to the proposed rule, EPA explained that the residue data requirements for antimicrobials were adapted from the conventional data requirements in subpart O (73 FR 59401). For uses of conventional pesticides, other than uses in agriculture, part 158 states that ''[residue chemistry] [d]ata may be required . . . if residues may occur in food or feed as a result of the use.'' (40 CFR 158.1410(b)(2)). The regulation also makes clear that this requirement applies whether or not a tolerance is needed under FFDCA section 408. The regulation specifies that ''most products used in or near kitchens require residue data for risk assessment purposes even though tolerances may not be necessary in all cases.'' (Id.)

The commenters' concern that the residue chemistry requirements exceeded EPA's jurisdiction under the FFDCA is addressed in Unit IV.

B. Complete Transference of the Antimicrobial into Food

1. *Comment.* The commenter believes that additional clarification is needed concerning EPA's statement, ''in the absence of data [the Agency will] evaluate the need for a tolerance or tolerance exemption by assuming complete transference of the chemical into food over the lifetime of the treated product.''

2. *EPA's response.* Complete transference refers to an assumption that the Agency would initially make regarding the migration of antimicrobial residues from an impregnated food contact material to the food contacting that material over the typical use life of the antimicrobial-impregnated material. The worst-case assumption is that 100 percent of the antimicrobial residues resulting from use at the maximum registered rate transfers into the food, which is then used to estimate a conservative dietary exposure. If the aggregate risk calculated using this conservative assumption, from use of the antimicrobial in question, is less than EPA's level of concern, then no measured data are needed. If the aggregate risk meets or exceeds EPA's level of concern, then chemical-specific data quantifying residue migration to refine this dietary exposure component may be required. To refine the exposure, the applicant may choose to perform one or more of the FDA protocols to estimate migration rate into food stimulants (see document ID number EPA–HQ–OPP–2008–0110–0013). Alternatively, or subsequently, the applicant may choose to conduct a chemical-specific nature of the residue on surfaces study and a migration study investigating actual impregnated materials using representative foods.

C. Alternative Formats for Residue Chemistry Data Requirements Table

1. *Comment.* Two different commenters suggested two different options as alternative approaches to the antimicrobial residue chemistry data requirement table proposed by EPA. One of the commenters separated the residue chemistry data requirements into two tables, referred to as Part 1 and 2 (ACC comment, identified in the

docket by document ID number EPA–HQ–OPP–2008–0110–0088.10, p. 7). The other commenter suggested a single table format (CSPA Comment, identified in the docket by document ID number EPA–HQ–OPP–2008–0110–0086.2).

2. *EPA's response.* All three of the commenter-suggested tables had the same five ''Supporting Information'' studies as the first section of the table proposed by EPA, but with various mixtures of ''R,'' ''CR,'' and ''NR.'' In the final rule, EPA has retained the same Supporting Information of the first section of the residue chemistry table as proposed. However, EPA has adopted the commenters' suggestion for a tiered format in the last two sections of the residue chemistry table. After review, EPA believes the commenters' suggested tiered approach is more suitable to antimicrobials than that proposed by EPA. All three of the commenters' tables suggested that Tier I consist of a ''Screening-level dietary exposure assessment.'' Although an applicant may opt to conduct a dietary exposure assessment, EPA does not consider this to be a data requirement. Applicants often conduct a dietary exposure assessment to understand the dietary risks before submitting an application to EPA. If submitted, EPA would review the assumptions used by the applicant and compare them to EPA's modeling. If the applicant's modeling indicates that dietary risk is likely to meet or exceed the Agency's level(s) of concern, the applicant may decide to continue on to Tier II or III. Therefore, EPA has not added a requirement to conduct a dietary exposure assessment.

Both the Part 1 Table and the single table suggested that Tier II consist of a ''Refined dietary exposure assessment.'' As is the case for the commenter's suggested Tier I ''Screening-level dietary exposure assessment,'' this is optional for the applicant; therefore, EPA has not added a requirement to conduct a refined dietary exposure assessment.

Both the Part 1 Table and the single table suggested that Tier 3 consist of nature of residue on surface, bioaccumulation, magnitude of residue, residue analytical method, and storage stability. These are each addressed individually as follows:

i. *Nature of residue on surface.* The Agency agrees that this study is applicable and a valuable addition to the data set necessary to support registration and risk assessment of antimicrobial uses on/in food-contact surfaces and impregnated materials (treated articles). EPA has added this study to the final residue chemistry data requirements table in part 158, subpart W.

ii. *Bioaccumulation.* EPA believes that the commenters intended that this study apply only to fish and that the bioaccumulation study required for ecological effects should substitute for the nature of the residue on surface study for aquatic uses or indoor/outdoor raw agricultural commodity uses. EPA has found that the fish bioaccumulation study is often not useful for residue chemistry purposes because characterization of fish residues is only required if the bioconcentration (of total residues) factor is > 1,000. The fish bioaccumulation study has not been adopted by EPA for residue chemistry. Of much more use to residue chemistry and retained in this final rule, are the fish metabolism and magnitude of the residue studies in fish described in OPPTS Guideline 860.1400.

iii. *Magnitude of residue (MOR).* Commenters proposed this study by the very general title ''Magnitude of residue.'' EPA considers MOR to be any study designed to quantify ''how much'' of the residues of concern will result in food, on surfaces, in water, etc., following use of an antimicrobial according to label directions. The commenters stated in a footnote to this study that, in the case of food-contact sanitizers and treated articles, MOR would consist of a migration study. Because food-contact sanitizer and treated article uses comprise at least 80 percent of all antimicrobial food uses, EPA has retained the migration study and the food-handling study by name but has moved them to a different tier. All the remaining proposed types of MOR studies are much more rarely required due to characteristics such as the use pattern and/or physicochemical properties of the antimicrobial in question. For that reason, the following have been grouped as ''Higher tiered'' studies in the final rule: Nature of the residue in plants, nature of the residue in livestock, residue analytical methods for tolerance enforcement, multiresidue method testing, potable water, fish, irrigated crops, meat/milk/poultry/eggs, crop field trials, processed food or feed, and anticipated residues.

iv. *Residue analytical method.* EPA agrees with the commenters that an analytical method for data collection is required whenever magnitude of the residue studies are required. The Agency has retained this study in the final Residue Chemistry Table.

v. *Storage stability.* EPA agrees with the commenters that storage stability data are required whenever magnitude of the residue studies are required. The Agency has retained this study in the final Residue Chemistry Table.

The Part 2 Table did not recommend requiring a Refined Dietary Exposure Assessment. Rather, its Tier 2 consists of studies entitled nature of the residue in commodity, nature of the residue in livestock, residue analytical methods for enforcement of tolerances, multiresidue analytical method, magnitude of the residue: In commodities, in water, and in meat/milk/poultry/eggs, storage stability, and anticipated residues. EPA agrees that all of these studies should be required and has retained all of them in the highest tier in the final Residue Chemistry Table. Note that two of the commenter-suggested studies (nature of the residue in commodity and magnitude of the residue in commodities) were considered applicable only to raw agricultural commodities (RACs) treated via a fruit and vegetable rinse; whereas, the analogous EPA data requirements apply to both crop plants and metabolically-active RACs. The data requirements in EPA's final rule easily subsume the studies suggested by a commenter in Part 2. The commenters feel that EPA only has authority to require residue data for RACs of plants treated by a fruit or vegetable rinse whereas EPA interprets FIFRA and FFDCA, as amended by FQPA, to mean that data may be required for any use if necessary to support registration of any use under FIFRA (see Units XVI.A. and IV.).

As evidenced by the recommendation to divide EPA's single proposed data requirement table into two tables (Parts 1 and 2), the commenters believe the data requirements are distinctly different depending on the use pattern of interest. While this is sometimes the case, the Agency has found that there is much overlap between which studies are necessary to characterize the dietary exposure potentially resulting from a given use. This is why the test notes provide the conditions under which each study is required, likely to be required, or not required. EPA has historically used and currently uses a single data requirement table for each scientific discipline; doing so permits the interrelationships between use pattern, tiering, and data needs to be fully evident.

The commenters did not account for data needed to estimate dietary exposure associated with uses that do not require a FFDCA section 408 tolerance or exemption (see Unit XVI.A. and Unit IV.). The commenters also did not account for data needed to estimate dietary exposure from food residues inadvertently resulting from, but not limited to, discharges of antimicrobial-treated water from indoor industries, leaching from preserved lumber, or

treatment of food crops when a public health claim is made on the label.

XVII. SAR and QSAR, and the OCSPP (formerly OPPTS) Integrated Testing Vision

This unit summarizes the significant public comments and EPA's response to those comments. A more detailed discussion can be found in the Response to Comments Document available in the docket to this rule.

A. Guidance on Policies, Procedures, and Processes

1. *Comment.* A commenter asked EPA to provide clear guidance on its policies, procedures, and processes on the use of alternative technologies such as SAR and QSAR, and the WOE approach. In addition, the commenter stated that EPA should also provide education and training on these approaches.

2. *EPA's response.* The Agency encourages applicants to create submissions that include predictive techniques such as SAR and QSAR to fulfill data requirements. As described in the white paper to the proposed rule, entitled, ''Use of Structure-Activity Relationship (SAR) Information and Quantitative SAR (QSAR) Modeling For Fulfilling Data Requirements for Antimicrobial Pesticide Chemicals and Informing EPA's Risk Management Process'' (see document ID number EPA–HQ–OPP–2008–0110–0045), an important part of the applicant's submission is the rationale. The rationale, or WOE evaluation, is the part of the submission that explains the applicant's belief as to why and how the predictive data would fulfill the data requirement. The WOE approach requires a critical analysis of the entire body of available data for consistency and biological plausibility. In support of a request that predictive data be considered, the applicant would need to explain why it believes the surrogate data or the modeling are appropriate for the intended use and are of sufficient completeness and quality, and therefore would fulfill the data requirement. The Agency would evaluate each submission with a WOE rationale on a case-by-case basis.

The general types of information that are considered appropriate for a WOE approach would include:

- *Sufficiency of data.* Studies that completely characterize both the effects and exposure of the agent have more credibility and support than studies that contain data gaps.
- *Quality of the data.* Potentially relevant studies are judged for quality and studies of high quality are given more weight than those of lower quality.
- *Evidence of causality.* The degree of correlation between the presence of an agent and some adverse effect is an important consideration.

Regarding SAR/QSAR, the white paper to the proposed rule (p. 30) discusses the five criteria set by the OECD for evaluating a model. EPA encourages submitters to follow the established criteria set by OECD, and show how the model is validated for that particular pesticide chemical structure as a measure of the model's applicability.

Different computer software programs are used to estimate/predict different hazards (see: *http://www.epa.gov/oppt/sf/tools/methods.htm*). This means that predictive software models for different scientific disciplines are not at the same level of development. The Agency has long standing experience in predicting (modeling) physical-chemical properties, environmental fate, ecotoxicity, and experience in predicting carcinogenesis for certain classes of chemicals. However, the Agency is still gaining experience to become familiar with predictive approaches that look at other human health endpoints (e.g., reproductive, developmental), which have not been widely used at EPA. Given the different stages of predictive software development, EPA would expect to undertake a case-by-case evaluation of submitted WOEs. EPA encourages the use of integrated approaches that combine the knowledge from existing data bases about the chemical of interest with data from appropriate surrogate chemicals.

EPA agrees that guidance on the policies, procedures, and processes for using alternative approaches such as SAR/QSAR is needed. In developing such a guidance document for pesticides, EPA sought to harmonize its approach with that of Canada's PMRA . The guidance document was issued as a North American Free Trade Agreement guidance document in 2012. This guidance document adheres to the five OECD principles that were discussed in the white paper and is now considered to be the definitive source of information for applicants seeking to use SAR and QSAR approaches for fulfilling data requirements for pesticide registration. For information, see *http://www.epa.gov/oppfead1/international/naftatwg/guidance/guidance.htm.*

B. Integrating SAR/QSAR Within the Data Requirements Rule

1. *Comments.* One commenter argued that there should be an explicit statement that SAR and QSAR can be considered to fulfill data requirements. Another commenter had concerns on codifying the use of SAR in 40 CFR part 158, subpart A since that would mean that ''SAR/QSAR Techniques would be applicable to conventional, biochemical and microbial, and antimicrobials pesticide chemicals.'' Another commenter requested that SAR/QSAR be fully integrated within the rule.

2. *EPA's response.* EPA has and will continue to consider accepting SAR/QSAR to fulfill its data requirements on a case-by-case basis. Acceptance would be based on the information provided and most especially on the supporting rationale submitted to EPA. The Agency would evaluate the information submitted to determine if the applicant has provided information that is of sufficient quality and completeness. The Agency notes that validation of QSAR models is necessary before the predictions from those models can be fully integrated into the testing requirements. To that end, QSAR models must be inclusive of pesticide toxicology data and chemical structures. Until these models become customized with pesticide information, full incorporation of predictive tools likely will be limited to a case-by-case basis.

EPA agrees that if use of SAR/QSAR were to be codified in subpart A, that it would be applicable to all pesticide chemicals. At this time, EPA is not codifying the use of SAR and QSAR in subpart A.

XVIII. Guidelines

This unit summarizes the significant public comments and EPA's response to those comments. A more detailed discussion can be found in the Response to Comments Document available in the docket to this rule.

A. Commenters' Concerns with Guidelines

1. *Comment.* Several commenters indicated their belief that the current Harmonized Guidelines have significant problems, which include:

- Lack of guidelines could create an unevenness from one company to another in how the data requirements are applied.
- Data requirements for which guidelines are not available.
- Older, outdated guidelines that need revision.
- Draft guidelines that need to be finalized.
- Older exposure guidelines that do not include information about the Human Studies Review Board.
- Guidelines that were adopted without the opportunity for public comment.

According to the commenters, lack of current guidelines could create an unevenness from one company to another in how the data requirements are applied. The commenter argued that the Agency needs to provide current, consistent, and reliable guidance and standards for each data requirement. The commenters recommended that EPA finalize all of its guidelines before the final rule is published per the recommendation from OMB.

2. *EPA's response.* EPA's Harmonized Test Guidelines are publicly-available at *http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm.* The Harmonized Guidelines contain recommendations on how to conduct a study that is most likely to provide the information needed by EPA for making a registration decision.

The Harmonized Guidelines are guidance. The guidelines themselves do not impose mandatory requirements. Applicants are not required to submit studies developed according to the guidelines to fulfill a data requirement. However, EPA encourages applicants to use the guidelines. These guidelines were developed to provide applicants, who would be conducting the studies, with recognized approaches for developing high quality data, guidance on evaluating and reporting data, definition of terms, and suggested study protocols. It would not be possible to address every conceivable circumstance that could occur when conducting a particular study. Instead the guidelines provide a framework that provides recommended approaches for conducting studies while offering flexibility and accommodation for individual circumstances where appropriate. EPA has reviewed and accepted many studies, on a case-by-case basis, that were not conducted in accordance with current guidelines, but which provided suitable information for risk assessment purposes.

Since guidelines cannot account for every conceivable circumstance, EPA, for certain studies, proposed a ''required'' or ''highly suggested'' protocol submission and review step in the test notes to the tables in the proposed rule. Generally, these pertain to those studies that are ''newer'' or have not been routinely conducted. Given that the applicant community and contracting laboratories would have less experience in conducting these kinds of ''newer'' studies, protocol submission, review, and meetings about proposed protocols are beneficial to both the applicant and EPA, and help assure that the study submitted for review should provide the information needed by EPA for its registration decision.

EPA acknowledges that in some instances there are: Data requirements for which guidelines are not available; outdated guidelines that need revision; and draft guidelines that need to be finalized. Ideally, up-to-date final guidelines would be available for every data requirement. Up-to-date guidelines increase the possibility that EPA will receive useful data and that applicants can produce such data in the most cost-efficient and consistent manner. However, given the rapidly evolving scientific methods for conducting toxicity, exposure, and ecological studies with pesticides, study guidelines often need frequent updating to include the latest techniques and methods. Moreover, the need for openness and transparency means that developing a guideline or updating an existing one can be a lengthy process. In a letter to CropLife America (June 26, 2009), (Ref. 12) the Agency discussed the timeframe for developing the Terrestrial Field Dissipation Guideline (835.6100), which spanned 15 years. During that time period, there were presentations to the SAP, at various symposia, including ones conducted by the American Chemical Society and the American Society of Agronomy, and to a workshop in Washington, DC co-hosted by EPA and Canada's Pest Management Regulatory Agency.

Thus, the reality is that test guidelines will always be a work in progress. At the same time, EPA is implementing a regulatory program under FIFRA and FFDCA section 408 under which it must make timely decisions on the safety of pesticide products based on toxicity and exposure testing. Guidance on optimal testing procedures remains an Agency goal but the absence of testing guidelines is not a barrier to the imposition of testing requirements necessary to make the required statutory findings.

In 2008, OMB, during its Executive Order 12866 review of the proposed rule, recommended that certain draft guidelines be finalized before publishing the Antimicrobial Data Requirements final rule. These guidelines were:

- Applicator product use information (OPPTS 875.1700).
- Post application product use information (OPPTS 875.2700).
- Indoor surface residue dissipation (OPPTS 875.2300).
- Non-dietary ingestion (OPPTS 875.3000).

In the proposed rule (73 FR 59382, October 8, 2008), EPA discussed that the publicly-available versions of these draft guidelines were available on the SAP portion of EPA's Web site *http://www.epa.gov/scipoly/sap/meetings/1998/march/contents.htm.* Since the two product use information related guidelines (875.1700 and 875.2700) are expected to provide similar guidance for the narrative descriptions that the related data requirements call for, EPA intends to update them together.

The indoor surface residue dissipation draft guideline (875.2300) will be updated before issued in final form to account for new advances in how exposure is measured and modeled and to provide more information on additional methods. EPA intends to revise the draft guideline to expand the methods for antimicrobial uses, and has begun to work with EPA's ORD to develop additional methods (e.g., one current project is to develop guidance for testing in small scale air chambers). EPA is also consulting with the Consumer Product Safety Commission (CPSC) to review their sampling methods for similar products (e.g., chemicals leaching from fabrics).

Also, as previously discussed, the proposed data requirement referencing the non-dietary ingestion guideline (identified as 875.3000) is not included in the final post-applicator exposure table in § 158.2270. As a result, that draft guideline is no longer referenced in part 158. (See Unit XIII.D.).

In addition, as noted in the proposed rule, EPA notes that it has reviewed and accepted many studies, on a case-by-case basis, that were not conducted in accordance with current final guidelines, but which serve its needs and provide suitable information for risk assessment purposes. The guidelines themselves do not impose mandatory requirements. Instead, they present recognized standards for conducting acceptable tests, guidance on evaluating and reporting data, definition of terms, and suggested study protocols. The draft guidelines, therefore, serve as a starting point for developing study protocols. The Agency's scientists can also provide guidance to applicants, registrants, or task forces on aspects of study design that is often discussed at pre-protocol submission meetings. The Agency's scientists are always willing to work with individual applicants or registrants to develop study designs to fulfill data requirements.

EPA acknowledges that the guidelines for dermal and inhalation exposure studies need revisions to account for new advances in how exposure is measured and modeled. To provide needed information to the public and applicants, EPA will change the way these guidelines are referenced on the Harmonized Guidelines Web site by

adding links to the SAP and Human Studies Review Board (HSRB) meetings at which the changes needed to conduct one of these studies were publicly discussed.

Since the publication of the proposed rule on October 8, 2008, EPA has worked to update and finalize a number of guidelines. In the **Federal Register** of April 15, 2009 (74 FR 17479) (FRL–8352–8), EPA issued a Notice of Availability describing updates to 16 environmental fate guidelines.

In the **Federal Register** of January 27, 2010 (75 FR 4380) (FRL–8437–2), EPA published four draft product performance guidelines for comment (i.e., 810.2000, 810.2100, 810.2200, and 810.2300). These four guidelines were developed over an extended period of time with multiple levels of review across divisions and program offices in EPA, expert external peer review by the FIFRA SAP, and discussions with and comments from the regulated community. After soliciting public comment in 2010, EPA announced the availability of the final guidelines in the **Federal Register** of March 16, 2012 (77 FR 15750) (FRL–9332–4). Many of the technical changes described in these four guidelines have been in use by the Agency for several years.

Three additional Product Performance Guidelines (i.e., 810.2400, 810.2500, and 810.2600) published for public comment on September 15, 2011 (76 FR 57031) (FRL–8879–1), and in the **Federal Register** of June 27, 2012 (77 FR 38280) (FRL–9349–5), EPA announced the availability of the final guidelines.

Also in the **Federal Register** of June 27, 2012 (77 FR 38282) (FRL–9333–1), EPA announced the availability of 26 Ecological Effects Test Guidelines in Series 850, and Groups B, C, D and F. In finalizing the guidelines, EPA changed the numbering and/or titles of certain guidelines, and split or merged other guidelines. EPA continues to work to revise the remaining Ecological Effects Test Guidelines, Group A, and anticipates finalizing many of these guidelines in 2013.

Before finalizing a guideline, EPA provides many opportunities for public comment. EPA's commitment to transparency is not new. Transparency allows all stakeholders to know what, how, and why EPA is adopting a guideline. EPA's procedures for developing a guideline is described in a Notice of Availability that published on August 28, 1996 (61 FR 44308) (FRL–5390–7):

- Guidelines under development (whether new or being substantially revised) are made available for public comment.
- Guidelines under development (whether new or being substantially revised) undergo an external peer review process. Most commonly, the peer review process would be a review by the FIFRA SAP.
- Reformatted guidelines (no substantial revisions) are not subject to review and comment.
- Public review and comment is also used when EPA guidelines are being harmonized with OECD guidelines.

B. Harmonization of Guidelines With OECD

1. *Comment.* EPA should harmonize its guidelines with those of OECD.

2. *EPA's response.* EPA agrees with this comment and is continuing to harmonize guidelines, to the extent practicable, as they are revised. As noted on its Web site *http://www.epa.gov/pesticides/science/guidelines.htm,* EPA has several harmonization activities underway with the OECD. The Master List of Harmonized Test Guidelines includes a reference to an OECD guideline, once harmonized. All harmonized OECD test guidelines (*http://www.epa.gov/epahome/exitepa.htm*) fall under the OECD Mutual Acceptance of Data decision, which calls for acceptance for regulatory use by all OECD member nations. Additionally, under 40 CFR 158.70(d)(2), acceptance of testing conducted in accordance with OECD protocols is described.

Harmonized test guidelines reduce the burden on chemical producers and conserve scientific resources, including the minimal use of laboratory test animals. They also form a basis for work sharing and cooperation among all OECD countries. U.S. experts are engaged in harmonization activities through OECD to revise toxicology and ecotoxicology test guidelines. These revisions will emphasize reduction, refinement, or replacement of animal testing, while incorporating the latest advances in science. Animal welfare concerns and international regulatory needs are being considered in the course of these revisions of the test guidelines. In addition, EPA is actively engaged in OECD's development and harmonization efforts for guidelines to address environmental fate, endocrine disruptor screening, and efficacy of antimicrobial pesticides.

Tests conducted in accordance with the requirements and recommendations of the applicable OECD protocols can be used to develop data necessary to fulfill the data requirements. However, some of the OECD recommended test standards, such as test duration and selection of test species, are less restrictive than those recommended by EPA. When using OECD protocols, applicants should be careful to observe the test standards so that the data generated will satisfy the EPA data requirements.

C. Guidelines Specific to Antimicrobials

1. *Comment.* The commenter claimed that guidelines specific to antimicrobials are needed.

2. *EPA's response.* EPA agrees that for certain scientific disciplines or certain studies antimicrobial-specific guidance may be needed. The data required to demonstrate product performance would be very different for an insect repellent or a termiticide versus that needed for sanitizers and disinfectants. Exposure studies could be conducted differently for an antimicrobial used in a food-processing plant versus a conventional pesticide sprayed on an agricultural field. Exposure studies could also be conducted via the same method: A spray can with an insecticide is assessed using the same techniques as a spray can with a disinfectant, with any differences in the assessment being attributed to actual use conditions, such as, indoors versus outdoors or surfaces sprayed. For other scientific disciplines such as toxicology or product chemistry, generally, with a few exceptions, the guidance would be the same. A carcinogenicity, developmental, or reproductive toxicity study would be conducted similarly for an antimicrobial or a conventional pesticide. However, as noted in Unit X.F., the Ames assay may not be useful for assessment of mutagenic potential of antimicrobial pesticides.

XIX. Endangered Species Assessments

This unit summarizes the significant public comments and EPA's response to those comments. A more detailed discussion can be found in the Response to Comments Document available in the docket to this rule.

A. Endangered Species Assessment for Antimicrobials

1. *Comment.* The commenter argued that EPA needs to recognize the manner in which antimicrobials may result in environmental exposure and the regulations under statutes other than FIFRA in order to promote an effective and efficient approach to regulating antimicrobial pesticides with regard to endangered and threatened species. According to the commenter, antimicrobials are not applied directly to the environment, but environmental exposures from antimicrobial pesticides result from point-source discharges or

slow release from pesticide-containing materials.

2. *EPA's response.* EPA agrees that there are differences between antimicrobial pesticides and agricultural pesticides. As discussed in the proposed rule (October 8, 2008, 73 FR 59425), for agricultural pesticides, there is generally greater specificity relative to where a pesticide may be used compared to antimicrobial pesticides. Agricultural pesticides are typically used on crops. As part of its endangered and threatened species assessment, EPA extracts information on county-level crop occurrence and acreage within counties of particular crops from the most recent USDA National Agricultural Statistics Services' Census of Agriculture. Because antimicrobial pesticides are typically not applied directly to the environment, it is easier to delineate and overlay agricultural pesticide use with endangered or threatened species locations than to delineate and overlay antimicrobial pesticides use. Nevertheless, wood preservatives, antifoulant paints and coatings, and other antimicrobial uses, including uses in swimming pool water, industrial slimicides used in recirculating water cooling towers, and paper mills, have the potential for environmental exposures. The Agency is working to refine its endangered species assessment for antimicrobial pesticides to account for the unique mechanisms involved in application and use of antimicrobial pesticides, and the different routes through which antimicrobial pesticides enter the environment.

EPA recognizes that antimicrobials, like any other pesticide product, may be subject to other Federal, State and local laws. FIFRA requires that, before a pesticide may be lawfully sold or distributed in the United States, the product must be registered by EPA, unless the product is exempt from registration requirements. Prior to registering a pesticide product, EPA must first ensure that the pesticide, when used according to label directions, can be used without posing unreasonable risks to humans and the environment. The registration of a pesticide product, whether it is an antimicrobial or other type of pesticide product, is considered an ''action'' subject to the Endangered Species Act (ESA). The ESA requires all Federal agencies to ensure that any action they permit or authorize will not result in likely jeopardy to the continued existence of endangered or threatened species, or destroy or adversely modify habitat designated as critical by the U.S. Fish and Wildlife Service (FWS) or National Marine Fisheries Service (NMFS).

In order to ensure EPA's actions are consistent with the ESA, the Agency must assess the potential for both direct and indirect effects to any potentially exposed threatened or endangered species and critical habitat, independent of whether exposure results from a point-source discharge or the slow release of a pesticide containing material. If effects may occur, EPA consults with the FWS or NMFS to determine whether there may be jeopardy to the species or destruction or adverse modification to habitat designated as critical.

B. Method for Conducting Endangered Species Assessments

1. *Comment.* A commenter claimed that EPA/OPP does not have a mature program currently in place for antimicrobial environmental risk assessment generally. More specifically, the commenter contended that EPA does not have a program in place for assessing potential impacts on endangered and threatened species relevant to antimicrobials and their uses. The commenter argued that until EPA scientifically substantiates data requirements to use in estimating antimicrobial environmental exposures and modeling and the potential for risks from such exposures, it will not be feasible to make any meaningful determinations on potential impacts to endangered species. The commenter concluded that it is thus premature for the EPA to determine how it should approach antimicrobials with regard to endangered species.

2. *EPA's response.* EPA disagrees with the commenter. EPA has a robust program for completing antimicrobial environmental risk assessments, as outlined in the preamble to the proposed rule (73 FR 59405). Environmental fate studies evaluate the mobility, distribution and dissipation of a pesticide in various compartments of the environment, such as water, soil, air, and sediment. Ecological effects data are used by the Agency to determine the toxicological hazards of pesticides to various nontarget organisms, such as birds, mammals, fish, bees, terrestrial and aquatic invertebrates, and plants. The required environmental fate studies and ecological effects (both plant and animal) data provide the foundation for an environmental risk assessment. EPA's environmental risk assessment for antimicrobials combines environmental fate studies with ecological effects data to determine the potential of the pesticide to cause harmful effects to nontarget organisms and plants. The data requirements that will be codified in the final rule will provide sufficient information for EPA to perform an ecological risk assessment.

EPA/OPP's process for assessing the potential risks of a pesticide to federally-listed threatened or endangered species and their designated critical habitat is described in the document titled ''Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency—Endangered and Threatened Species Effects Determinations'' (Ref. 13). Appendix A to that document—''Overview of OPP's Screening-Level Ecological Risk Assessment Process for Antimicrobial Pesticides''—explains both the data needed and the process that would be used by EPA to assess potential risks to endangered and threatened species from antimicrobial pesticides.

EPA's assessment of potential impacts on endangered and threatened species begins with a screening level assessment to determine if there is a potential concern. When the screening-level ecological risk assessment raises potential concerns related to a listed species, EPA then conducts a species-specific evaluation to refine the assessment. The more refined assessment should involve clear delineation of the action area associated with the proposed use of the pesticide and best available information on the temporal and spatial co-location of the listed species with respect to the action area. EPA notes that with the publication of the proposed rule, the discussion in Appendix A is out of date. In response to comments received on the proposed antimicrobial data requirements, EPA indicated it is no longer relying on its proposed approach classifying use patterns as high/low or minimal/significant exposure uses with regard to ecological effects testing. However, the Agency's basic approach to endangered species risk assessments, which combine environmental fate studies with ecological effects data to determine the potential of the pesticide to cause harmful effects to endangered species, has not changed. In addition, the Agency will conduct an assessment for antimicrobial pesticides with down-the-drain uses, as described in response to comment 134.1 in the Response to Comments Document in the docket. The codified data requirements and the down-the-drain assessment will extend EPA's Antimicrobial Division's ability to understand the potential impacts of antimicrobial pesticides on endangered species.

EPA cannot wait to comply with the ESA until newer, more advanced, models are available or additional data needs are determined. Federal agencies must comply with the ESA by performing their assessments and analyses using the best scientific and commercial data available. As a part of Registration Review, EPA is conducting species-specific environmental risk assessments that will allow EPA to determine whether the antimicrobial pesticide product has ''no effect'' or ''may affect'' federally-listed threatened or endangered species (listed species) or their designated critical habitats. When an assessment concludes that a pesticide product's use ''may effect'' a listed species or its designated critical habitat, the Agency will consult with the FWS and/or NMFS, as appropriate.

XX. Endocrine Disruption

This unit summarizes the significant public comments and EPA's response to those comments. A more detailed discussion can be found in the Response to Comments Document available in the docket to this rule.

1. *Comment.* The commenters noted that EPA did not include any studies to assess endocrine disruption effects.

2. *EPA's response.* The commenter is correct that EPA did not include, within proposed part 158, subpart W, studies whose sole purpose is to assess endocrine disruption effects in avian and aquatic species. The Agency is also not including such studies in this final rule.

With regards to toxicology data requirements, as required by FIFRA and FFDCA, EPA reviews a toxicological data base of numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. EPA reviews these data and selects the most sensitive endpoints for relevant risk assessment scenarios from the existing toxicological data base.

With regards to ecotoxicity data requirements, as required by FIFRA and FFDCA, EPA reviews a nontarget organism data base of numerous studies to assess potential adverse outcomes from exposure to chemicals. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. EPA reviews these data and selects the most sensitive endpoints for relevant risk assessment scenarios from the existing nontarget organism database.

Through a separate effort, the Agency has also developed a screening battery to identify chemicals that may have effects on the hormone systems of humans and wildlife. As required under FFDCA section 408(p), the Agency developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a ''naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.'' The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier I consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier I screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Between October 2009 and February 2010, EPA issued test orders/data call-ins for 58 pesticide active ingredients and 9 inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain post-application agricultural scenarios. This list should not be construed as a list of known or likely endocrine disruptors.

Under FFDCA section 408(p) the Agency must screen all pesticide chemicals, including antimicrobials. Accordingly, EPA anticipates issuing future EDSP test orders/data call-ins for all pesticide active ingredients.

For further information on the EDSP including the status and test guidelines, please visit the Web site: *http://www.epa.gov/endo/.*

XXI. Effective Date of Final Antimicrobial Data Requirements

This unit summarizes the significant public comments and EPA's response to those comments. A more detailed discussion can be found in the Response to Comments Document available in the docket to this rule.

1. *Comment.* Several commenters have expressed concern over when the final rule would take effect. One commenter stated that compliance with the Administrative Procedures Act requires EPA to apply any final rulemaking on data requirements for antimicrobials only to applications submitted after the effective date; otherwise, EPA would be promulgating the final rule retroactively. The commenter also asserted that EPA should be consistent in its implementation of effective dates, noting that EPA did not impose new data requirements on pending conventional pesticide registrants when the conventional pesticide rules were revised. A second commenter suggested that registrations pending at the time of the final rule publication be given conditional registration under section 3(c)(7) of FIFRA or under section 3(c)(5) if the requirements of part 161 have been met, and that implementation of the part 158, subpart W data requirements occur at the time of periodic registration review. Another commenter noted that EPA has provided reasonable notice to registrants and recommends that EPA implement the rule as soon as technically feasible. A different commenter questioned whether additional Pesticide Registration Improvement Act (PRIA) registration fees would be required for pending applications if the registrant did not meet new data requirements and withdrew the application, or if the Agency issued a determination that it cannot grant the application.

2. *EPA's response.* EPA will follow an approach similar to that used for conventional pesticides following the promulgation of that portion of 40 CFR part 158.

As previously discussed, the final rule for antimicrobials contains 11 ''new'' data requirements. ''New'' means that the data requirement has never been required, or has rarely been required on a case-by-case basis and has not been routinely considered during the Agency's evaluation of the data needed for the purpose of risk assessment. The new data requirements being codified include eight that were proposed and three that have been added based on public comments received about the proposed rule.

EPA recognizes that during early implementation of 40 CFR part 158, subpart W not all application packages may have all of the newly-required data. Therefore during early implementation of 40 CFR part 158, subpart W, EPA will accept for review and evaluation application packages that may not have all of the newly required data in appropriate cases supported by adequate justification. This early implementation period could extend up to 2 years post-promulgation for situations in which a more time-intensive new study is missing but could be less for other situations, such as for less time-intensive new studies. The applicant should address the issue of timing (i.e., why the data are not yet submitted and when the data can be submitted) with respect to any missing newly-required data, in their justification.

EPA is statutorily required to evaluate the proposed pesticide thoroughly to ensure that it will not unreasonably harm human health or the environment. For pesticides needing FFDCA section 408 tolerances, EPA is statutorily required to make a safety finding that the pesticide can be used with ''reasonable certainty of no harm.'' In cases where the application may not have all the required data, EPA would evaluate whether a registration determination or a safety finding can be made based on the available data or on the results of other studies in the pesticide's data base. If there is insufficient information, and if the data base does not provide information on the endpoints that would be tested, or data provided by the applicant or information in the data base shows evidence of effects, EPA may not be able to make a registration decision or safety finding. In such cases, the application may be denied or the applicant may choose to withdraw the application pending completion of the needed data. In some cases, conditional registrations may be appropriate for consideration. Among other things, a determination that the proposed use will not significantly increase the risk of unreasonable adverse effects on the environment will need to be made. If EPA can make that determination and the other elements for a conditional registration are met, then a conditional registration may be appropriate and the new data required as a condition of registration. If there is a basis for granting a conditional registration, then the timeframe for conditioning the registration would be determined based on factors such as the required studies involved and the length of time required to conduct those studies.

Importantly, it should be noted that acceptance of an application for processing during early implementation of 40 CFR part 158, subpart W, that does not result in a conditional registration, does not permanently relieve the applicant from providing the newly required data. Based on the particular case involved, the Agency will employ appropriate mechanisms, for example, through a data call-in or through the registration review process, to ensure the generation and submission of any missing newly-required data.

With respect to pending applications that are withdrawn, additional Pesticide Registration Improvement Act (PRIA) registration fees will generally only be required if the applicant seeks to pursue the action again by submitting a new application (and addressing the deficiencies in the original application). In withdrawal situations, the Agency provides a refund for any work that the Agency did not perform on the application following a withdrawal. Similarly, a determination that the application cannot be granted does not require additional PRIA registration fees. In that case, additional fees will only be incurred if the application is subsequently withdrawn or denied, and the applicant seeks to pursue the action again and submits a new application.

XXII. Economic Analysis

This unit summarizes the significant public comments and EPA's response to those comments. A more detailed discussion can be found in the Response to Comments Document available in the docket to this rule.

A. Comparing Estimates of Cost of the Proposed Rule

1. *Comment.* A commenter performed an independent economic analysis (EA) for the proposed rule. According to the commenter's analysis, the cost of proposed part 158, subpart W is greater than that estimated by the EPA. In addition, the unit test costs and frequency of tests used in the commenter's analysis are different than EPA's.

2. *EPA's response.* EPA reviewed the commenter's analysis and based on that review revised the EA for the final rule. EPA's evaluation of the commenter's EA indicated there were the following differences between the two EAs:

- The cost estimates used for the studies,
- Overhead costs were included by the commenter, but not by EPA,
- Costs for Registration Review (see Unit XXII.C.).

The differences between the cost of the proposed rule as estimated by the commenter and the cost as assessed by the Agency for new registrations are explained in the following subunits.

i. *How data requirement costs are calculated.* The annual cost of a data requirement is the product of three factors: Unit test cost, probability of the test being required, and the number of registrations in the industry per year for the registration type and use. That is: ''Industry cost of a data requirement = Unit test cost x test probability x number of registrations.'' These costs are summed for all data requirements, uses, and registration types to get the total annual cost of the data requirements for the industry.

ii. *Differences in unit test costs.* EPA acknowledges that there are significant differences between the Agency's analysis and the commenter's analysis regarding the unit test costs. According to the commenter's EA, the costs were provided to them by their client's technical consultants, and are ''based on quotes from laboratories, actual experience, and professional judgment.'' The commenter did not provide sufficient information with which to evaluate the commenter's test cost estimates. Additionally, EPA notes that having all test cost estimates ending in zero could be indicative of estimation.

EPA's unit test costs for each data requirement were obtained by contacting established contract research organizations (CROs) to assess what the labs would charge to conduct studies according to specific designs provided by EPA, or as specified in OPPTS guidelines (now OCSPP guidelines). Upper and lower cost estimates were requested. For each test, the upper cost estimates from each CRO were averaged to obtain a high average estimate. A similar calculation was done for the lower cost estimate. EPA's estimate is the average of the high and low average estimates.

iii. *Test costs and overhead costs.* The commenter added 30 percent to their test cost estimates to account for the overhead of the registrants managing and overseeing the tests they contract to the labs. EPA acknowledges that there are costs other than test costs associated with registering and maintaining the registrations of pesticide products. Overhead is not a new cost, attributable to the rule, and EPA does not believe that overhead costs will change significantly as a result of codifying data requirements for antimicrobials. EPA does not include overhead costs in its economic analyses of data requirements rules because the Agency accounts for other registration costs such as overhead

in the Information Collection Request (ICR) for FIFRA Section 3 Registration under the Paperwork Reduction Act.

iv. *Test probabilities.* EPA's test probabilities (the probabilities of tests being required for a registration action) were based on a sample of 70 actual antimicrobial registration actions out of 90 relevant new registration actions during the 6 year period beginning 2000 and ending 2005, supplemented with EPA's scientific judgment. The time period (2000–2005) was chosen for EPA's EA because the analysis in the EA was started in 2006. The commenter claims to have based the test probabilities used to make their estimates on a sample of 29 registration review cases (not new registrations) occurring between 2008 and 2010.

v. *Factors which drive costs for new registrations.* To determine the influence of the previously-discussed factors on the difference between the commenter's and EPA's estimates, EPA performed the following analysis on the data requirements costs and incremental costs using the same unit test costs and test probabilities used in the proposed rule:

- To account for the effect of the unit test costs on the data requirements costs and incremental costs, EPA substituted the commenter's unit test costs without overhead into EPA's analysis of the proposed rule using EPA's test probabilities and number of registrations. If there were no changes, this would indicate that the test costs were not driving the differences in estimates.
- To account for the effect of test probabilities and number of registrations, EPA substituted the commenter's unit test costs with overhead into EPA's analysis. In this case, the difference between the EPA's and the commenter's analysis is contained in the test probabilities and number of registrations. If there were no changes, this would indicate that the test probabilities and number of registrations were not driving the differences between the two analyses. Since the commenter includes overhead in their analysis, overhead was included in this comparison to make other things equal so that the differences in test probabilities and number of registrations could be isolated.

vi. *Results.* The results of the factor analysis are presented in the following Table 1.

TABLE 1—COMPARISON OF DATA REQUIREMENT COSTS AND FACTORS FOR NEW REGISTRATIONS

Factors	A	B	C	D
Unit Test Costs according to:	EPA Proposed Rule	Commenter without overhead.	Commenter with 30 percent overhead.	Commenter with 30 percent overhead.
Test Probabilities according to:	EPA	EPA	EPA	Commenter.
Number of Registrations according to:	EPA	EPA	EPA	Commenter.
Data Requirement Cost according to Proposed Rule ($ millions).	$15.0	$19.9	$25.5	$25.9.
Cost of Proposed Rule (Incremental Costs) ($ millions).	$3.9	$7.6	$9.8	$9.2.

Column A exhibits the data requirements and incremental costs from EPA's EA of the proposed rule. In column B, the data requirements and incremental costs are calculated using the commenter's unit test costs without overhead costs, but EPA's test probabilities and number of registrations. Column C is the same as column B, but with overhead costs included. Finally, column D exhibits the data requirements and incremental costs with overhead as calculated by the commenter.

The result of the first factor analysis is demonstrated by comparing column A to column B. In this case, the difference between the two columns is the unit test costs. Inserting the commenter's unit test costs, without overhead, into the cost estimates with EPA's test probabilities and number of registrations leads to over a 30 percent increase in data requirements cost and a nearly 100 percent increase in incremental costs.

The result of the second factor analysis is demonstrated by comparing columns C and D. In this case, the difference between the two columns is in the test probabilities and number of registrations. While individual test probabilities may be different in EPA's and the commenter's analyses, the overall effect of the products of test probabilities and number of registrations, when summed with the unit test costs, including overhead, are similar in both of these analyses. The resulting differences in data requirements cost and incremental costs are less than 2 percent and about 6 percent, respectively. Therefore, EPA concludes that any differences in test probabilities and number of registrations used as input parameters in the calculations do not have a significant effect on the total data requirement cost of new registrations.

Comparisons across columns A, B, and C also provide information on the portion of the cost difference accounted for by overhead costs. Columns A, B, and C compare the cost of data requirements using the unit test cost estimates of EPA and those of the commenter with and without overhead. The overhead costs account for more than one-half of the difference in the total cost of the data requirements, but less than 40 percent of the difference in incremental costs (the incremental cost is the increase in costs between the baseline (the existing data requirements in part 161) and proposed part 158, subpart W).

From this comparison, EPA makes the following conclusions. First, differences in test probabilities and number of registrations do not have a significant impact on the cost of the rule. Second, even if EPA and the commenter used the same probabilities and test costs, inclusion of overhead costs by the commenter would result in a 30 percent difference in costs. Finally, when the overhead costs are removed from the commenter's analysis, differences in unit test costs between EPA and the commenter account for most of the differences in the estimates of the cost of the rule for new registrations.

vii. *Revised test costs.* In light of the results of the comparison between EPA's and the commenter's EA, EPA sought to verify its unit test cost estimates. To examine the costs submitted by ACC, EPA resurveyed the cost of conducting studies for 30 data requirements: The criteria for selecting which test's cost to update included how the difference in estimates would impact on the cost of the rule, the magnitude of the differences in estimates, and the age and source of EPA's estimates. EPA's data gathering

methodology is reproducible, and based on actual data. EPA does not adjust the lab's cost estimates, i.e., the costs are used as obtained from the laboratory. Under the Information Quality Act (IQA), EPA must ensure and maximize the quality, objectivity, utility, and integrity of the data used in its analyses.

The resurveyed test costs are used in the EA for the final rule. EPA is using its cost estimates because it has revised its most relevant and oldest unit test cost estimates. In addition, the commenter did not provide a basis or sufficient explanation that would meet the standards of the IQA to justify EPA's accepting the commenter's costs. For additional information see response to comment 40.1 in the Response to Comments Document and the final economic analysis, both in the docket.

B. Impact on Small Businesses

1. *Comment.* A commenter claimed that EPA underestimated costs, is not fully complying with the Regulatory Flexibility Act (RFA) and the Small Business Regulatory Enforcement Fairness Act (SBREFA), and must prepare an Initial Regulatory Flexibility Assessment (IRFA). In addition, the commenter argued that small businesses will be adversely affected, that there will be an ''increased disparity between registrants and a more uneven playing field,'' and finally, that a SBREFA analysis should have been conducted.

2. *EPA's response.* EPA acknowledges that the cost of the data requirements would likely be a larger percentage of a small business's revenues, but did not find that the rule would have a significant adverse economic impact on a substantial number of small firms.

A regulatory flexibility analysis examines the type and number of small entities potentially subject to the rule, recordkeeping and compliance requirements, and significant regulatory alternatives, among other things. RFA, as amended by SBREFA, requires EPA to consider the economic impact of proposed rules on small entities. RFA requires EPA to prepare an IRFA for each proposed rule, when the rule will have a significant economic impact on a substantial number of small entities.

To comply with RFA, EPA did a retrospective analysis of what the additional costs would have been on actual new registrations if the proposed rule had been in effect during 2000–2005. This analysis did not indicate a significant impact on a substantial number of small entities; instead, the analysis indicated that 5 percent of small firms (25 out of 500) are likely to experience some impact and only 2.8 percent of small firms (14 out of 500) are likely to experience an economic impact of 3 percent or more of gross sales. Based on this analysis, EPA certified that the proposed rule would not have a significant adverse economic impact on a substantial number of small firms. As a result, EPA did not have to conduct an IRFA nor convene a SBREFA Panel for the proposed part 158, subpart W rule.

In the EA for the final rule, EPA reestimated the SBREFA analysis with revised unit test costs and changes in data requirements.

- About 23 small firms (almost 5 percent) are likely to experience an economic impact of 3 percent or more of gross sales, and
- About 26 small firms, (over 5 percent) are likely to experience an economic impact of 1 percent or more of gross sales.

Hence, had these results been estimated at the proposal stage, EPA would still have concluded that there would not be a significant impact on a substantial number of small entities.

C. Cost of New Data Requirements on Registration Review

1. *Comment.* A commenter stated that EPA has not accurately stated the potential costs and benefits, as required by Executive Order (EO) 12866. In particular, EPA has not included the impact of incremental costs of new data requirements on registration review, or the cost of consultations. The commenter also claims that under the Paperwork Reduction Act (PRA), EPA should include the paperwork burden costs of registration review for existing registrants.

2. *EPA's response.* EO 12866 requires the Agency to submit to OMB for review significant regulatory actions. EPA complied with EO 12866 during 2008 by submitting drafts of both the economic analysis and the proposed rule to OMB. The changes that were made to the proposed rule as the result of OMB's review were included in the docket for the proposed rule. The Agency notes that one purpose of soliciting comments on the economic analysis at the proposal stage is to get input on where the Agency might improve the economic analysis.

The commenter is not correct in asserting that EPA did not include the impact of incremental costs. The Agency has captured the anticipated costs necessary for complying with the regulations. See the final Economic Analysis (Ref. 1) in the docket for a more detailed discussion, particularly sections 5.3 and 5.5.

The commenter is correct in that the costs of fulfilling the 11 ''new'' data requirements during registration review were not considered in the Agency's economic analysis of the proposed part 158, subpart W data requirements. EPA agrees with the commenter that registrants of existing antimicrobial products will incur costs during registration review. In fact, EPA relied on the 2005 EA conducted for the Registration Review Rule. When registration review was proposed, EPA prepared an economic analysis of that program, which estimated the cost of data requirements and paperwork burden according to what would likely be required in registration review for existing registrants. The 2005 registration review EA estimate of data requirement costs for existing antimicrobial pesticides was based on what would likely be required for a sample of antimicrobial active ingredients. This would have included all tests that would have been required at that time, i.e., those in current practice whether or not in part 158.

However, proposed part 158, subpart W included ''new'' tests, which were not anticipated when the economic analysis of the registration review process was completed. In a final economic analysis for part 158, subpart W, EPA addresses the additional registration review costs for these 11 ''new'' studies, as well as other changes from the proposed rule to the final rule, including changes made as a result of the comments received. The incremental impact for Registration Review is $ 6.8 million.

The commenter is also correct that EPA did not include the cost of consultation in its economic analysis. Consultations are longstanding, commonly used, and valuable processes in EPA's Pesticide Program and are beneficial to both EPA and the applicants. However, consultations are not mandatory, and based on comments received EPA has removed all references to consultations from the final data requirements tables. See Unit V.C. for additional information on the use and purpose of consultations.

XXIII. References

As indicated under **ADDRESSES**, a docket has been established for this rulemaking under docket ID number EPA–HQ–OPP–2008–0110. The following is a listing of the documents that are specifically referenced in this proposed rule. The docket includes these documents and other information considered by EPA in developing this rule, 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 documents, please consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

1. USEPA, Final Economic Analysis of Changes in Data Requirements for Antimicrobial Pesticides, (March 13, 2013).
2. USEPA, ''Data Requirements for Pesticide Registration; Final Rule'' (49 FR 42856, October 26, 2007)(FRL–8106–5).
3. ACC Biocides Panel; ''Regulation of Antimicrobials that are Indirect or Secondary Direct Food Additives;'' (February 2, 2006).
4. CMA Biocides Panel; ''Comments on EPA's September 17, 1999 Proposed Rule on Registration Requirements for Antimicrobial Pesticide Products and Other Pesticide Regulatory Changes for Codification; (January 18, 2000).
5. ACC Biocides Panel; Memorandum to Frank Sanders, ''EPA's Current Interpretation of the Antimicrobial Reform Technical Corrections Act and Section 2(bb) of FIFRA is Inconsistent with the Statutes;'' (November 3, 2000).
6. ACC Biocides Panel; ''EPA/FDA Jurisdiction for Food Contact Antimicrobials;'' (July 17, 2003).
7. Grizzle, Charles L.; representative of Albright & Wilson Americas, Inc., letter to Lynn R. Goldman; (September 11, 1997).
8. ChemReg International, L.L.C.; Tiered Testing for Risk Assessment of Antimicrobial Pesticides; (September 12, 2002).
9. Goldberg, Seth; ''Section 2(bb) of FIFRA; Dual Jurisdiction Over Food Contact Antimicrobials; (April 27, 2001).
10. ACC Biocides Panel; ''Comments on The Preliminary Risk Assessment for 1,4-Bis(bromoacetoxy)-2-butene (BBAB);'' (August 6, 2001).
11. ACC Biocides; Hasmukh C. Shah letter to Frank T. Sanders; (August 3, 2000).
12. Edwards, Deborah; OPP Response to CropLife letter of May 29, 2009; (June 26, 2009).
13. Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency—Endangered and Threatened Species Effects Determinations (January 2004) (*see www.epa.gov/espp/consultation/ecorisk-overview.pdf*).
14. Portier; SAP Waiver; (April 4, 2011).

XXIV. FIFRA Review Requirements

In accordance with FIFRA section 25(a), a draft of this final rule was submitted to the FIFRA SAP. EPA requested the FIFRA SAP to waive its review of the final rule based on the fact that the SAP, in 2008, had waived review of the proposed rule. The final rule does not contain any new scientific issues warranting additional review by the SAP. The SAP waived its review on April 4, 2011, stating that ''[t]he final rule does not contain scientific issues that the Panel has not previously considered'' (Ref. 14).

In accordance with FIFRA section 25(a), EPA has submitted a draft of the final rule to the appropriate Congressional Committees and the Secretary of the Department of Agriculture. There were no comments in response to these submissions.

In accordance with FIFRA section 21(b), EPA submitted a draft of the final rule to the Secretary of Health and Human Services (HHS), and their comments were reviewed and addressed in this final rule.

XXV. Statutory and Executive Order Reviews

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

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a ''significant regulatory action'' because the Office of Management and Budget (OMB) determined that this action might raise 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 OMB for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket for this action as required by Executive Order 12866.

EPA has prepared an EA of the potential costs associated with this action, entitled ''Final Economic Analysis of Changes in Data Requirements for Antimicrobial Pesticides'' (Ref. 1), a copy of which is in the docket. This final EA evaluates the potential benefits and costs expected as a result of registrations and registration reviews. The EA is briefly summarized here.

In its analysis, the Agency considered the potential, additional costs for the registration of new antimicrobial pesticides or new uses of currently registered antimicrobial pesticides, as well as the potential, additional costs incurred during the registration review of existing antimicrobial pesticides.

Based on comments received during the public comment period, the following changes were made to the rulemaking, and are therefore reflected in the final EA:

- One proposed data requirement will not be codified: Non-dietary ingestion exposure. The test cost is $75,000. In the proposed rule, EPA expected to receive the test 0.8 times per year, representing an annual industry savings of $63,125.
- EPA revised certain of the data requirements from ''NR'' or ''CR'' to ''R,'' or vice-versa.

Based on comments received, three new data requirements were added: Simulation test to assess the biodegradability of chemicals discharged in wastewater, simulation test—aerobic sewage treatment: Activated sludge units, and nature of the residue on surfaces. The rationale for these three new studies is described in Unit III.B.

The estimated costs for both registration review and for a registration action for the three newly-required data requirements are:

1. *Simulation tests to assess the biodegradability of chemicals in discharged wastewater and simulation test—aerobic sewage treatment: activated sludge units.* Both of these studies are used as part of the down-the-drain analysis for antimicrobials. The studies are conditionally required for all use patterns, except for the aquatic areas use pattern, for which the study is not required. EPA does not have an estimate for the cost of either of these studies; instead, for the EA, EPA used the value $33,000, which is the cost of the porous pot test. The Agency expects, however, that the cost of the simulation tests will be less than this amount. For registration review, EPA expects to receive the porous pot test or one of the simulation tests up to 8.5 times per year, for an annual industry cost of $280,500. For new registrations, EPA expects to receive either of the studies up to 7.5 times per year, for an annual industry cost of $247,500. The total annual cost is $528,000.

2. *Nature of residue on surfaces.* This test is part of the residue chemistry data requirements, and is conditionally required for all use pattern categories. The test cost is $95,000. For registration review, EPA expects to receive this test 1.3 times per year, for an annual industry cost of $118,750. For new registrations, EPA expects to receive this test up to 0.5 times per year, for an annual industry cost of $44,333. The total annual cost is $163,083.

Many test notes for data requirements were revised based on comments received. Data requirements for certain use patterns were changed from ''NR'' or ''CR'' to ''R,'' while others were changed from ''R'' to ''CR.'' Because the cost of the rule depends, in part, on the probabilities of the tests being required, these revisions have resulted in a modification of the cost of the rule. Instead of estimating the cost of each change individually, the Agency reestimated the potential cost of the regulation as a whole, taking into account the changes discussed previously.

Based on comments received, EPA has updated the unit test costs for 30

selected tests. The criteria for selecting which test's cost to update included:

- How changing the cost estimates would impact on the cost of the rule,
- The magnitude of the difference between EPA's cost estimate and the commenters' cost estimate, and
- The length of time since EPA's cost estimate was last updated.

EPA estimated the annual cost of registering a new antimicrobial pesticide or new use of currently-registered antimicrobial pesticides, taking into account both the changes in data requirements and in unit test costs. Both the total annual industry costs and the newly-imposed costs were estimated. The updated test costs plus exposure and other test costs revisions since the proposed rule increased the cost of the rule by about 23 percent compared to the proposed rule. The estimated total annual industry costs of the final rule is expected to be about $19.3 million, which is approximately 29 percent higher than the cost of the proposed rule. The difference between the baseline costs (the existing data requirements that were codified in 1984) and the cost of the Agency's current practices is about $1 million annually. The difference between the baseline costs and the final rule costs, i.e., the incremental costs, is approximately $8.2 million annually. Under the final rule, the average cost per registration action of a new antimicrobial active ingredient is approximately $1 million to $5 million.

For existing chemicals, data requirements in part 158, subpart W are relevant to the registration review program which began to replace the reregistration program in 2006 as a means of systematically reevaluating existing registrations against the standards of FIFRA.

EPA has evaluated the impact of the data requirements being codified in this final rule on registrants of existing chemicals undergoing registration review whose active ingredient data bases do not contain all of the new data requirements. The average additional cost of registration review as a result of the new data requirements is estimated to be about $588,000 for wood preservatives, $284,000 for food and indirect food uses, and $260,000 for all other uses. For registration review, the total annual cost is $6.8 million.

As required, EPA conducted an analysis of the impact of this final rule on small businesses, as discussed in the Unit XXV.C.

B. Paperwork Reduction Act (PRA)

The information collection requirements contained in this rule have been submitted for approval to OMB under the PRA, 44 U.S.C. 3501 *et seq.* At the time of the proposed rule, EPA prepared a supporting statement for amending an ICR, entitled ''Data Requirements for Antimicrobial Pesticides (Proposed Rule)'' and identified by EPA ICR No. 2318.01, a copy of which is in the docket.

Under PRA, ''burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency.

The information collection activities related to the submission of data to EPA in order to register, amend or retain a new or existing pesticide product or obtain a tolerance for that product are already approved by OMB under PRA. As such, the supporting statement only addresses the proposed changes to the data requirements that impact the information collection activities related to antimicrobial pesticides. The procedures for submitting data to EPA under FIFRA and FFDCA are not changed in this proposal, and are already approved by OMB in the following ICRs:

1. *Tolerance ICR.* Data Submission Activities Associated with Tolerance Actions (currently approved under OMB Control No. 2070–0024 (EPA ICR No. 0597));
2. *Registration ICR.* Data Submission Activities Associated with the Application for a New or Amended Registration of a Pesticide (currently approved under OMB Control No. 2070–0060 (EPA ICR No. 0277)); and
3. *Reregistration, Special and Registration Review ICR.* Data Submission Activities Associated with the Generation of Data for Special Review or Registration Review (currently approved under OMB Control No. 2070–0174 (EPA ICR No. 2288)).

These three program activities are an integral part of the Agency's pesticide program, including antimicrobial pesticides, and the corresponding ICRs are regularly renewed every 3 years as required by PRA. The total estimated average annual public reporting burden currently approved by OMB for these various activities range from 8 hours to approximately 3,000 hours per respondent, depending on the activity and other factors surrounding the particular pesticide product.

In the supporting statement the Agency estimates that the typical, current annual paperwork burden for registrants per antimicrobial pesticide registration is 194 burden hours and $12,631. The total annual registrant paperwork burden and costs for data submission activities for antimicrobial pesticides applicants and registrants will be updated accordingly in the ICRs specified in this discussion during the next, appropriate ICR renewal cycle.

An agency may not conduct or sponsor, and a person is not required to respond to an information collection request unless it displays a currently valid OMB control number, or is otherwise required to submit the specific information by a statute. The OMB control numbers for EPA's regulations codified in Title 40 of the Code of Federal Regulations, after appearing in the preamble of the final rule, are further displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in a list at 40 CFR 9.1.

C. Regulatory Flexibility Act (RFA)

The RFA, 5 U.S.C. 601 *et seq.,* 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, 5 U.S.C. 551–553, 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 final 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, which is based on either the maximum number of employees or on the sales for small businesses in each industry sector, as defined by a 6-digit NAICS code, and for this rule is a producer of pesticide products (NAICS 32532), antifoulants (NAICS 32551), antimicrobial pesticides (NAICS 32561) or wood preservatives (NAICS 32519), importers of such products, or any person or company who seeks to register an antimicrobial, antifoulant coating, ballast water treatment, or wood preservative pesticide or to obtain a tolerance for such a pesticide;
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; or
3. A small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this final rule on small

entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The factual basis for the Agency's determination is presented in the small entity impact analysis prepared as part of the Economic Analysis for this final rule (Ref. 1), and is summarized in this unit.

EPA has determined that this rulemaking does not impact any small governmental jurisdictions or any small not-for-profit enterprise because these entities are rarely pesticide applicants or registrants. As such, EPA has assessed the impacts on small businesses. Some of the small entities directly regulated by this rulemaking are in the pesticide and other agricultural chemical manufacturing industry sector (NAICS code 325320). Firms in this sector are considered small under the SBA definition if they employ 500 or fewer people. The economic analysis for the final rule specifies the NAICS code used for each of the firms analyzed.

EPA estimates that 750 unique parent companies constitute the total universe of pesticide antimicrobial registrants. Of these, based on the SBA definition of a small business and the available sales data for these firms, EPA estimates that 500, or approximately 67 percent, qualify as a small business. When considering both registration review and new registrations, on average each year about 30 small businesses would have incurred additional costs under this rule. EPA estimates that:

- About 23 small firms (almost 5 percent of the 500 small antimicrobial firms) subject to this regulation are likely to experience an economic impact of 3 percent or more of gross sales,
- About 3 small firms (0.6 percent of the 500 small antimicrobial firms) subject to this regulation are likely to experience an economic impact of greater than 1 percent but less than 3 percent of sales revenues, and
- About 3 small firms (0.6 percent of the 500 small antimicrobial firms) subject to this regulation are likely to experience an economic impact of greater than 0 percent, but less than 1 percent of sales revenues.

In addition, there are also opportunities for small entities to lower their potential costs. The proposed data requirements in many instances are tiered, with higher-tiered testing triggered on the results of lower-tiered testing. EPA encourages registrants to consult with the Agency to ensure that only the required data is submitted. If available, open literature or the same tests on similar products, or alternative means to meet data requirements, such as QSAR, can be submitted for Agency consideration. Some firms may have surrogate data or they may share the cost of generating data. These may present opportunities for cost savings by small entities, and all other applicants as well, while allowing the Agency to fulfill its role of making pesticide regulatory decisions that protect the general population, sensitive sub-populations, and the environment.

D. Unfunded Mandates Reform Act (UMRA)

Title II of UMRA, 2 U.S.C. 1531–1538, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. EPA has determined that this final rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. As described in Unit XXV.A., the incremental costs for this final rule is estimated at approximately $8.3 million (for registration actions) and $6.8 million (for registration review) per year for the private sector, which is below the $100 million threshold. Since State, local, and tribal governments are rarely pesticide applicants, this rule is not expected to significantly or uniquely affect small governments, nor does this rule contain any regulatory requirements that might significantly or uniquely affect small governments. Accordingly, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

This rule 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. As stated previously, State, local, and tribal governments are rarely pesticide applicants.

E. Executive Order 13132: Federalism

This action does not have federalism implications, because 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 (64 FR 43255, August 10, 1999). Since States or local governments are rarely pesticide applicants or registrants, this final rule would seldom affect a State or local government. Thus, Executive Order 13132 does not apply to this rule.

In the spirit of Executive Order 13132 and consistent with EPA policy to promote communication between EPA, and State and local governments, EPA specifically solicited comment on the proposed rule from State and local officials. EPA did receive comments on substantive parts from local sanitation districts and associations representing their interests. Their comments are addressed in the Response to Comments Document in the docket, and, as appropriate, revisions were made for the final rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Government Implications

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). At present, no tribal government holds, or has applied for, a pesticide registration. Thus, Executive Order 13175 does not apply to this action. In the spirit of the Order, and consistent with EPA policy to promote communications between the Agency and Indian tribes, EPA specifically solicited comment on the proposed rule from tribal officials. No comments were received.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This final rule is not subject to Executive Order 13045 because it is not economically significant as defined by Executive Order 12866, and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This rule does not propose an environmental standard that is intended to have a negatively disproportionate effect on children. To the contrary, this rule is intended to provide added protection to children from antimicrobial pesticide risk. EPA will use the data and information obtained by this action to carry out its mandate under FFDCA to give special attention to the risks of pesticides to sensitive groups in early lifestages, especially infants and children.

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

This final rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to

have any adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of NTTAA, 15 U.S.C. 272 note, directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

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

Executive Order 12898 (59 FR 7629, February 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 final 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.

XXVI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report to each House of the Congress and the Comptroller General of the United States. 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 rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 158

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

40 CFR Part 161

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 19, 2013.

Bob Perciasepe,

Acting Administrator.

Therefore, under the authority of 7 U.S.C. 136–136y and 21 U.S.C. 346a, 40 CFR Chapter I is amended as follows:

PART 158—[AMENDED]

■ 1. The authority citation for part 158 continues to read as follows:

Authority: 7 U.S.C. 136–136y and 21 U.S.C. 346a.

■ 2. Revise § 158.1(c)(4) to read as follows:

§ 158.1 Purpose and scope.

* * * * *

(c) * * *

(4) *Antimicrobial pesticides.* Subparts A, B, C, D, and W of this part apply to antimicrobial pesticides.

■ 3. In § 158.100 revise the heading of paragraph (a); revise paragraph (b); redesignate paragraph (c) as paragraph (e); revise newly redesignated paragraph (e) and add new paragraphs (c) and (d), to read as follows:

§ 158.100 Pesticide use patterns.

(a) *General use patterns for conventional, biochemical, and microbial pesticides.* * * *

(b) *Pesticide use site index for conventional, biochemical, and microbial pesticides.* The Pesticide Use Site Index for Conventional, Biochemical, and Microbial Pesticides is a comprehensive list of specific pesticide use sites. The index is alphabetized separately by site for all agricultural and all nonagricultural uses. The Pesticide Use Site Index associates each pesticide use site with one or more of the 12 general use patterns. It may be used in conjunction with the data tables to determine the applicability of data requirements to specific uses. The Pesticide Use Site Index for Conventional, Biochemical, and Microbial Pesticides will be updated periodically, and is available from the Agency or may be obtained from the Agency's Web site at *http://www.epa.gov/pesticides.*

(c) *Antimicrobial pesticide use patterns.* The general use patterns for antimicrobial pesticides are described in § 158.2201.

(d) *Pesticide use site index for antimicrobial pesticides.* The Pesticide Use Site Index for Antimicrobial Pesticides is a comprehensive list of specific antimicrobial use sites. The index is alphabetized by antimicrobial use sites, and associates each antimicrobial use site with one or more of the antimicrobial use patterns. It may be used in conjunction with the data tables to determine the applicability of data requirements to specific uses. The Pesticide Use Site Index for Antimicrobial Pesticides will be updated periodically, and is available from the Agency or may be obtained from the Agency's Web site at *http://www.epa.gov/pesticides.*

(e) *Determination of use pattern.* Applicants unsure of the correct use pattern for their particular product should consult the Agency.

§ 158.400 [Amended]

■ 4. In the table in § 158.400(d) remove the heading ''Efficacy of Antimicrobial Agents,'' and the entries 91–2 through 91–8 under that category.

■ 5. Add subpart W to read as follows:

Subpart W—Antimicrobial Pesticide Data Requirements

Sec.
158.2200 Applicability.
158.2201 Antimicrobial use patterns.
158.2203 Definitions.
158.2204 Public health and nonpublic health claims.
158.2210 Product chemistry.
158.2220 Product performance.
158.2230 Toxicology.
158.2240 Nontarget organisms.
158.2250 Nontarget plant protection.
158.2260 Applicator exposure.
158.2270 Post-application exposure.
158.2280 Environmental fate.
158.2290 Residue chemistry.

Subpart W—Antimicrobial Pesticide Data Requirements

§ 158.2200 Applicability.

Part 158, subpart W establishes data requirements for any pesticide product that is:

(a) A pesticide that is intended for use as an ''antimicrobial pesticide'' within the meaning of FIFRA sec. 2(mm)(1)(A), regardless of whether it also meets the criterion of FIFRA sec. 2(mm)(1)(B).

That criterion excludes from the definition any antimicrobial product that is intended for a food-use requiring a tolerance or exemption under FFDCA sec. 408 or a food additive regulation or clearance under FFDCA sec. 409. EPA will apply this subpart to all products intended for an antimicrobial use, purpose or function; the exclusion in FIFRA sec. 2(mm)(1)(B) does not exclude products from the data requirements of this subpart.

(b) A product that bears both antimicrobial and non-antimicrobial uses or claims. Such a product is subject to the data requirements for pesticides in subparts C through O, and U or V of this part with respect to its non-antimicrobial uses and claims, and to the requirements of this subpart with respect to its antimicrobial uses and claims.

(c) A wood preservative, including a product that is intended to prevent wood degradation problems due to fungal rot or decay, sapstain, or molds.

(d) An antifoulant, including a product that is intended to kill or repel organisms that can attach to underwater surfaces, such as boat bottoms.

§ 158.2201 Antimicrobial use patterns.

(a) *Antimicrobial use patterns.* The 12 general use patterns used in the data tables in this subpart are:

(1) Agricultural premises and equipment.

(2) Food-handling/storage establishments, premises and equipment.

(3) Commercial, institutional and industrial premises and equipment.

(4) Residential and public access premises.

(5) Medical premises and equipment.

(6) Human drinking water systems.

(7) Materials preservatives.

(8) Industrial processes and water systems.

(9) Antifoulant paints and coatings.

(10) Wood preservatives.

(11) Swimming pools.

(12) Aquatic areas.

(b) *Use site index.* The Pesticide Use Site Index for Antimicrobial Pesticides is a comprehensive list of specific antimicrobial use sites. The Index associates antimicrobial use sites with one or more of the 12 antimicrobial use patterns. It is to be used in conjunction with the data tables in this subpart to determine the applicability of data requirements to specific uses. The Antimicrobial Pesticide Use Site Index, which will be updated periodically, is available from the Agency or may be obtained from the Agency's Web site at *http://www.epa.gov/pesticides.*

§ 158.2203 Definitions.

The following terms are defined for the purposes of this subpart:

Disinfectant means a substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment.

Fungicide means a substance, or mixture of substances, that destroys fungi (including yeasts) and fungal spores pathogenic to man or other animals in the inanimate environment.

Microbiological water purifier means any unit, water treatment product or system that removes, kills or inactivates all types of disease-causing microorganisms from the water, including bacteria, viruses and protozoan cysts, so as to render the treated water safe for drinking.

Sanitizer means a substance, or mixture of substances, that reduces the bacteria population in the inanimate environment by significant numbers, but does not destroy or eliminate all bacteria. Sanitizers meeting Public Health Ordinances are generally used on food contact surfaces and are termed sanitizing rinses.

Sterilant means a substance, or mixture of substances, that destroys or eliminates all forms of microbial life in the inanimate environment, including all forms of vegetative bacteria, bacterial spores, fungi, fungal spores, and viruses.

Tuberculocide means a substance, or mixture of substances, that destroys or irreversibly inactivates tubercle bacilli in the inanimate environment.

Virucide means a substance, or mixture of substances, that destroys or irreversibly inactivates viruses in the inanimate environment.

§ 158.2204 Public health and nonpublic health claims.

(a) *Public health claim.* An antimicrobial pesticide is considered to make a public health claim if the pesticide product bears a claim to control pest microorganisms that pose a threat to human health, and whose presence cannot readily be observed by the user, including but not limited to, microorganisms infectious to man in any area of the inanimate environment. A product makes a public health claim if one or more of the following apply:

(1) A claim is made for control of specific microorganisms that are directly or indirectly infectious or pathogenic to man (or both man and animals). Examples of specific microorganisms include, but are not limited to: *Mycobacterium tuberculosis, Pseudomonas aeruginosa, Escherichia coli (E. coli), human immunodeficiency virus (HIV), Streptococcus, and Staphylococcus aureus.* Claims for control of microorganisms infectious or pathogenic only to animals (such as canine distemper virus or hog cholera virus) are not considered public health claims.

(2) A claim is made for the pesticide product as a sterilant, disinfectant, virucide, sanitizer, or tuberculocide against microorganisms that are infectious or pathogenic to man.

(3) A claim is made for the pesticide product as a fungicide against fungi infectious or pathogenic to man, or the product does not clearly state that it is intended for use only against nonpublic health fungi.

(4) A claim is made for the pesticide product as a microbiological water purifier or microbial purification system.

(5) A non-specific claim is made that the pesticide product will beneficially impact or affect public health at the site of use or in the environment in which it is applied, and:

(i) The pesticide product contains one or more ingredients that, under the criteria in 40 CFR 153.125(a), is an active ingredient with respect to a public health microorganism and there is no other functional purpose for the ingredient in the product; or

(ii) The pesticide product is similar in composition to a registered pesticide product that makes antimicrobial public health claims.

(b) *Nonpublic health claim.* An antimicrobial pesticide is considered to make a nonpublic health claim if the pesticide product bears a claim to control microorganisms of economic or aesthetic significance, where the presence of the microorganism would not normally lead to infection or disease in humans. Examples of nonpublic health claims include, but are not limited to: Algaecides, slimicides, preservatives and products for which a pesticidal claim with respect to odor sources is made.

§ 158.2210 Product chemistry.

The product chemistry data requirements of subpart D of this part apply to antimicrobial products covered by this subpart.

§ 158.2220 Product performance.

(a) *General*—(1) *Product performance requirement for all antimicrobial pesticides.* Each applicant must ensure through testing that his product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency may require, on a case-by-case basis, submission of product

performance data for any pesticide product registered or proposed for registration or amendment.

(2) *Product performance data for each product that bears a public health claim.* Each product that bears a public health claim, as described in § 158.2204(a), must be supported by product performance data, as listed in the table in paragraph (c) of this section. Product performance data must be submitted with any application for registration or amended registration.

(3) *Product performance data for each product that bears a nonpublic health claim.* Each product that bears a nonpublic health claim, as described in § 158.2204(b), must be supported by product performance data. Each registrant must ensure through testing that his product is efficacious when used in accordance with label directions and commonly accepted practices. The Agency reserves the right to require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration or amendment.

(4) *Determination of data requirements.* Subpart B of this part and § 158.2201 describe how to use the table in paragraph (c) of this section to determine the product performance data requirements for antimicrobial pesticide products.

(b) *Key.* R = Required; EP = End-use product.

(c) *Antimicrobial product performance data requirements table.* The following table shows the data requirements for antimicrobial product performance.

TABLE—ANTIMICROBIAL PRODUCT PERFORMANCE DATA REQUIREMENTS

Guideline No.	Data requirement	All use patterns	Test substance
810.2100	Sterilants—Efficacy Data Recommendations	R	EP
810.2200	Disinfectants for Use on Hard Surfaces—Efficacy Data Recommendations.	R	EP
810.2300	Sanitizers for Use on Hard Surfaces—Efficacy Data Recommendations.	R	EP
810.2400	Disinfectants and Sanitizers for Use on Fabrics and Textiles—Efficacy Data Recommendations.	R	EP
810.2500	Air Sanitizers—Efficacy Data Recommendations	R	EP
810.2600	Disinfectants for Use in Water—Efficacy Data Recommendations	R	EP

§ 158.2230 Toxicology.

(a) *General.* Subpart B of this part and § 158.2201 describe how to use the table in paragraph (g) of this section to determine the toxicology data requirements for an antimicrobial pesticide product. Notes that apply to an individual test, including specific conditions, qualifications, or exceptions are listed in paragraph (h) of this section.

(b) *Uses.* The applicant for registration must first determine whether the use is likely to result in pesticide residues in food or water and therefore consult the ''Food Use'' columns of the table in paragraph (g) of this section. Generally, if the residues of the antimicrobial result from an application to a surface or if incorporated into a material that may come into contact with food or feed, and residues may be expected to transfer to such food or feed, then the ''Indirect Food Uses'' columns is to be consulted.

(c) *Tiering of data requirements.* Applicants for registration of antimicrobials may perform tests in a tiered fashion. After the initially required tests are conducted, additional testing may be required if results of the initial tests trigger the need for additional data. Conditions that trigger the need for additional data are given in the test notes in paragraph (h) of this section.

(d) *200 parts per billion (ppb).* The 200 ppb level was originally used by the Food and Drug Administration with respect to the concentration of residues in or on food for tiering of data requirements for indirect food use biocides. The Agency has also adopted this same residue level for determining toxicology data requirements for indirect food uses of antimicrobial pesticides. The 200 ppb level is the concentration of antimicrobial residues in or on the food item.

(e) *Use of OSHA standards.* If EPA determines that industrial standards, such as the workplace standards set by the Occupational Safety and Health Administration (OSHA standards), provide adequate protection for a particular pesticide or a particular use pattern, additional toxicity data may not be required for that pesticide or the use pattern.

(f) *Key.* R = Required; CR = Conditionally required; NR = Not required; MP = Manufacturing-use product; EP = End-use product; TGAI = Technical grade of the active ingredient; TEP = Typical end-use product; PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabeled; Choice = choice of several test substances depending on studies required.

(g) *Antimicrobial toxicology data requirements table.* The following table shows the data requirements for toxicology. The test notes applicable to the data requirements in this table appear in paragraph (h) of this section.

TABLE—ANTIMICROBIAL TOXICOLOGY DATA REQUIREMENTS

Guideline No.	Data requirement	Food uses			Nonfood uses		Test substance		Test note No.
		Direct food uses	Indirect food uses (>200 ppb)	Indirect food uses (≤200 ppb)	Swimming pools, aquatic areas, wood preservatives, metal working fluids	All other nonfood uses	MP	EP	
Acute Testing									
870.1100	Acute oral toxicity—rat.	R	R	R	R	R	MP and TGAI.	EP and TGAI.	1, 2

TABLE—ANTIMICROBIAL TOXICOLOGY DATA REQUIREMENTS—Continued

Guideline No.	Data requirement	Food uses			Nonfood uses		Test substance		Test note No.
		Direct food uses	Indirect food uses (>200 ppb)	Indirect food uses (≤200 ppb)	Swimming pools, aquatic areas, wood preservatives, metal working fluids	All other nonfood uses	MP	EP	
870.1200	Acute dermal toxicity.	R	R	R	R	R	MP and TGAI.	EP and TGAI.	1, 2, 3
870.1300	Acute inhalation toxicity—rat.	R	R	R	R	R	MP and TGAI.	EP and TGAI.	2, 4
870.2400	Primary eye irritation—rabbit.	R	R	R	R	R	MP and TGAI.	EP and TGAI.	1, 2, 3
870.2500	Primary dermal irritation.	R	R	R	R	R	MP and TGAI.	EP and TGAI.	1, 2, 3
870.2600	Dermal sensitization.	R	R	R	R	R	MP and TGAI.	EP and TGAI.	1, 2, 3, 5
870.2600	Acute neurotoxicity—rat.	R	R	CR	R	CR	TGAI	TGAI	6, 11
Subchronic Testing									
870.3100	90-Day oral toxicity—rodent.	R	R	R	R	CR	TGAI	TGAI	8, 9, 15, 38
870.3150	90-Day oral toxicity—non-rodent.	R	R	CR	R	CR	TGAI	TGAI	10, 15
870.3200	21/28-Day dermal toxicity.	CR	CR	CR	CR	CR	TGAI	EP and TGAI.	12, 13
870.3250	90-Day dermal toxicity.	CR	CR	CR	CR	CR	TGAI	EP and TGAI.	7, 13, 14, 15
870.3465	90-Day inhalation toxicity—rat.	CR	CR	CR	CR	CR	TGAI	TGAI	7, 15, 16, 17
870.6200	90-Day neurotoxicity—rat.	R	R	CR	R	CR	TGAI	TGAI	6, 8
Chronic Testing									
870.4100	Chronic oral toxicity—rodent.	R	R	CR	R	CR	TGAI	TGAI	18, 19, 20
870.4200	Carcinogenicity—two rodent species—rat and mouse preferred.	R	R	CR	R	CR	TGAI	TGAI	19, 21, 22
Developmental Toxicity and Reproduction									
870.3700	Prenatal developmental toxicity—rat and rabbit preferred.	R	R	R	R	R	TGAI	TGAI	23, 24, 25, 26
870.3800	Reproduction and fertility effects.	R	R	R	R	R	TGAI	TGAI	26, 27, 28, 29
870.6300	Developmental neurotoxicity.	CR	CR	CR	CR	CR	TGAI	TGAI	28, 29, 30
Mutagenicity									
870.5100	Reverse mutation assay.	R	R	R	R	R	TGAI	TGAI	31, 32
870.5300 870.5375	*In vitro* mammalian gene mutation.	R	R	R	R	R	TGAI	TGAI	31, 33
870.5385 870.5395	*In vivo* cytogenetics.	R	R	R	R	R	TGAI	TGAI	31, 34
Special Testing									
870.7485	Metabolism and pharmacokinetics.	R	R	CR	R	CR	PAI or PAIRA.	PAI or PAIRA.	35, 39
870.7200	Companion animal safety.	CR	CR	CR	CR	CR	NR	Choice	36
870.7600	Dermal penetration.	CR	CR	CR	CR	CR	Choice	Choice	3, 37

TABLE—ANTIMICROBIAL TOXICOLOGY DATA REQUIREMENTS—Continued

Guideline No.	Data requirement	Food uses			Nonfood uses		Test substance		Test note No.
		Direct food uses	Indirect food uses (>200 ppb)	Indirect food uses (≤200 ppb)	Swimming pools, aquatic areas, wood preservatives, metal working fluids	All other nonfood uses	MP	EP	
870.7800	Immunotoxicity	R	R	R	R	R	TGAI	TGAI	8

(h) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (g) of this section:

1. Not required if test material is a gas or highly volatile liquid.

2. The six end-use product (EP) acute toxicity studies are required using the product as formulated for sale and distribution. In addition, if the EP label has directions for diluting the product, then, the applicant may also need to conduct certain of the acute toxicity studies using the highest concentration labeled for dilution (i.e., the least diluted product). The end-use dilution testing is in addition to the testing conducted on the EP.

3. Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5.

4. Data are required when the product consists of, or under conditions of use will result in, a respirable material (e.g., gas, vapor, aerosol or particulates).

5. Data are required if repeated dermal exposure is likely to occur under conditions of use.

6. For indirect food uses ≤ 200 ppb, and all other nonfood uses, data are required if the neurotoxicity screen in the 90-day oral rodent study or other data indicate neurotoxicity.

7. The 90-day dermal toxicity study and/or 90-day inhalation toxicity study are required if the Agency determines that dermal and/or inhalation exposure is the primary route of exposure.

8. All 90-day subchronic studies in the rodent can be designed to simultaneously fulfill the requirements of the 90-day neurotoxicity and/or immunotoxicity studies by adding separate groups of animals for testing of neurotoxicity and/or immunotoxicity parameters.

9. The 90-day study is required in the rodent for hazard characterization (possibly endpoint selection) and dose-setting for the chronic/carcinogenicity study. It is not required in the mouse, but the Agency would encourage the applicant to conduct a 90-day range finding study for the purposes of dose selection for the mouse carcinogenicity study to achieve adequate dosing and an acceptable study.

10. A 1-year non-rodent study (i.e., 1-year dog study) may be required if the Agency finds that a pesticide chemical is highly bioaccumulative and slowly eliminated. EPA may also require the appropriate metabolism and pharmacokinetic studies to evaluate more precisely bioavailability, half life, and steady state to determine if a longer duration dog toxicity study is needed.

11. Although the subchronic toxicity testing guidelines include measurement of neurological endpoints, such screens do not meet the requirement of the 90-day neurotoxicity study. For nonfood uses, if the 90-day study does not include a neurotoxicity screen, then the acute neurotoxicity study will be required.

12. Data are required if all of the following criteria are met:

i. The intended use of the antimicrobial pesticide product is expected to result in repeated dermal human exposure to the product.

ii. Data from a 90-day dermal toxicity study are not available.

iii. The 90-day dermal toxicity study has not been triggered.

13. EP testing is required if the product or any component of the product may increase dermal absorption of the active ingredient(s) or increases its toxic or pharmacologic effects, as determined by testing using the TGAI or based on available information about the toxic effects of the product or its components.

14. Data are required if the active ingredient in the product is known or expected to be metabolized differently by the dermal route of exposure than by the oral route, and a metabolite of the active ingredient is the toxic moiety.

15. A 90-day oral toxicity test is not required for heating, ventilation, air conditioning, and refrigeration systems (collectively referred to as HVAC&R). Instead, two 90-day toxicity tests, one by the dermal route and one by the inhalation route are required.

16. Data are required if there is the likelihood of significant repeated inhalation exposure to the pesticide as a gas, vapor, or aerosol.

17. Based on estimates of the magnitude and duration of human exposure, studies of shorter duration, e.g., 21- or 28-days, may be sufficient to satisfy this requirement. The prime consideration in determining the appropriateness of a shorter duration study is the likely period of time for which humans will be exposed.

18. Based on the positive results of the acute or 90-day neurotoxicity studies, or on other data indicating neurotoxicity, a chronic neurotoxicity study (i.e., a chronic study with additional neurotoxicity evaluations) may be required to provide information about potential neurotoxic effects from long-term exposures.

19. Studies which are designed to simultaneously fulfill the requirements of both the chronic oral and carcinogenicity studies (i.e., a combined study) may be conducted.

20. For indirect food uses ≤ 200 ppb, and all other nonfood uses, data are required if either of the following criteria are met:

i. The use of the pesticide is likely to result in repeated human exposure over a considerable portion of the human lifespan; or

ii. The use requires that a tolerance, tolerance exemption, or food additive regulation or clearance be established.

21. For indirect food uses ≤ 200 ppb, and all other nonfood uses, data are required if any of the following criteria, are met:

i. The use of the pesticide is likely to result in significant human exposure over a considerable portion of the human life span which is significant in terms of frequency, time, duration, and/or magnitude of exposure.

ii. The use requires that a tolerance, tolerance exemption, or food additive regulation or clearance be established.

iii. The active ingredient, metabolite, degradate, or impurity:

A. Is structurally related to a recognized carcinogen;

B. Causes mutagenic effects as demonstrated by *in vitro* or *in vivo* testing; or

C. Produces a morphologic effect in any organ (e.g., hyperplasia, metaplasia) in subchronic studies that may lead to a neoplastic change.

22. If the requirement for a carcinogenicity study in any species is modified or waived for any reason, then

a subchronic 90-day oral study in the same species may be required.

23. Testing in two species is required for all uses.

24. The oral route, by oral intubation, is preferred, unless the chemical or physical properties of the test substance, or the pattern of human exposure, suggest a more appropriate route of exposure.

25. Additional testing by other routes of exposure may be required if the pesticide is determined to be a prenatal developmental toxicant after oral dosing.

26. The developmental toxicity study in rodents may be combined with the two-generation reproduction study in rodents by using a second mating of the parental animals in either generation. Protocols must be approved by the Agency prior to the initiation of the study.

27. A two-generation reproduction study is required.

28. An information-based approach to testing is preferred, which utilizes the best available knowledge on the chemical (hazard, pharmacokinetic, or mechanistic data) to determine whether a standard guideline study, an enhanced guideline study, or an alternative study should be conducted to assess potential hazard to the developing animal. Applicants must submit any alternative proposed testing protocols and supporting scientific rationale to the Agency. Protocols must be approved by the Agency prior to the initiation of the study.

29. The use of a combined two-generation reproduction/developmental neurotoxicity study that utilizes the two-generation reproduction study in rodents as a basic protocol for the addition of other endpoints or functional assessments in the immature animal is encouraged.

30. A DNT study is required using a weight-of-evidence approach when:

i. The pesticide causes treatment-related neurological effects in adult animal studies (i.e., clinical signs of neurotoxicity, neuropathology, functional or behavioral effects).

ii. The pesticide causes treatment-related neurological effects in developing animals, following pre- or post-natal exposure (i.e., nervous system malformations or neuropathy, brain weight changes in offspring, functional or behavioral changes in the offspring).

iii. The pesticide elicits a causative association between exposures and adverse neurological effects in human epidemiological studies.

iv. The pesticide evokes a mechanism that is associated with adverse effects on the development of the nervous system (i.e., structure-activity-relationship (SAR) to known neurotoxicants, altered neuroreceptor or neurotransmitter responses).

31. To facilitate the weight-of-evidence determination for the pesticide's mutagenicity, in addition to those specifically listed in this table, the Agency requires submission of other mutagenicity test results that may have been performed. A reference list of all studies and papers known to the applicant concerning the mutagenicity of the test chemical must be submitted with the required studies.

32. Due to the nature of antimicrobials, if testing with bacterial strains has not been conducted, then testing using a mammalian cell assay such as the mouse lymphoma TK +/− assay is preferred. If reverse mutation assay testing with bacterial strains has already been conducted, and the testing was conducted at levels that did not cause toxicity to the bacterial strains tested, then the applicant may submit the study to fulfill this data requirement.

33. For the *in vitro* mammalian gene mutation study, there is a choice of assays using either mouse lymphoma L5178Y cell thymidine kinase (tk) gene locus, maximizing assay conditions for small colony expression and detection; Chinese hamster ovary (CHO) or Chinese hamster lung fibroblast (v79) cells, hypoxanthine-guanine phosphoribosyl transferase (hgprt) gene locus, accompanied by an appropriate *in vitro* test for clastogenicity; or CHO cells strains AS52, xanthine-guanine phosphoribosyl transferase (xprt) gene locus.

34. There is a choice of assays, but the micronucleus rodent bone marrow assay is preferred; the rodent bone marrow assays using metaphase analysis (aberrations) are acceptable.

35. Data are required when chronic toxicity or carcinogenicity studies are also required.

36. Data is required if the product label directs that it be applied to domestic animals, such as cats, dogs, cattle, pigs, and horses.

37. In the absence of dermal absorption data or a repeated dose dermal toxicity study, the assumption of 100 percent dermal absorption would be used in a risk assessment to determine if a dermal penetration study is required, and to identify the doses and duration of exposure for which dermal absorption is to be quantified.

38. Required for nonfood uses, if oral exposure could occur.

39. Data may be required if significant adverse effects are seen in available toxicology studies and these effects can be further elucidated by metabolism and pharmacokinetics studies.

§ 158.2240 Nontarget organisms.

(a) *General.* Subpart B of this part and § 158.2201 describe how to use the table in paragraph (c) of this section to determine the terrestrial and aquatic nontarget organisms data requirements for a particular antimicrobial pesticide product. Notes that apply to an individual test, including specific conditions, qualifications, or exceptions are listed in paragraph (d) of this section.

(1) Terrestrial and aquatic nontarget organism data are required to support the registration of most end-use and manufacturing-use antimicrobial products.

(2) Data are generally not required to support end-use products of a gas, highly volatile liquid, highly reactive solid, or a highly corrosive material.

(3) Data on transformation/degradation products or leachate residues of the parent compound are also required to support registration, if the transformation/degradation/degradation products or leachate residues meet one of the following criteria:

(i) More toxic, persistent, or bioaccumulative than the parent;

(ii) Have been shown to cause adverse effects in mammalian or aquatic reproductive studies; or

(iii) The moiety of concern (i.e., functional group in the parent chemical molecule that imparts adverse effects) remains intact.

(4) If an antimicrobial may be applied to a field crop, horticultural crop, or turf, then the data requirements in § 158.630 apply.

(5) For the purpose of determining data requirements, the all other use patterns category includes the following use patterns:

(i) Agricultural premises and equipment.

(ii) Food-handling/storage establishments, premises, and equipment.

(iii) Commercial, institutional and industrial premises and equipment.

(iv) Residential and public access premises.

(v) Medical premises and equipment.

(vi) Human drinking water systems.

(vii) Materials preservatives.

(viii) Swimming pools.

(b) *Key.* MP = Manufacturing use product; EP = End-use product; R = Required; CR = Conditionally required; NR = Not required; TGAI = Technical grade of the active ingredient; TEP = Typical end-use product; PAIRA = Pure active ingredient radiolabeled; a.i. = active ingredient.

(c) *Antimicrobial nontarget organism data requirements table.* The following table shows the data requirements for nontarget organisms. The test notes appear in paragraph (d) of this section.

TABLE—ANTIMICROBIAL NONTARGET ORGANISM DATA REQUIREMENTS

Guideline No.	Data requirement	Use pattern					Test substance		Test note No.
		Industrial processes and water systems	Antifoulant coatings and paints	Wood preservatives	Aquatic areas	All other use patterns category	MP	EP	
Tier One Testing									
850.2100	Acute avian oral toxicity.	R	R	R	R	R	TGAI	TGAI	1
850.1010	Acute freshwater invertebrates toxicity.	R	R	R	R	R	TGAI	TGAI	2
850.1075	Acute freshwater fish toxicity.	R	R	R	R	R	TGAI	TGAI	3
Higher Tier Testing									
Avian Testing									
850.2200	Avian dietary toxicity.	CR	CR	CR	CR	CR	TGAI	TGAI	4
850.2300	Avian reproduction.	CR	CR	CR	CR	CR	TGAI	TGAI	1, 6
Aquatic Organisms Testing									
850.1010	Acute freshwater invertebrates toxicity.	CR	CR	CR	CR	CR		TEP	2, 5, 7
850.1075	Acute freshwater fish toxicity.	CR	CR	CR	CR	CR		TEP	3, 5, 7
850.1025 850.1035 850.1045	Acute estuarine and marine organisms toxicity.	CR	R	CR	CR	CR	TGAI	TGAI	8, 9
850.1055 850.1075	Acute estuarine and marine organisms toxicity.	CR	CR	CR	CR	CR		TEP	5, 7, 8
850.1400	Fish early-life stage.	R	R	R	R	R	TGAI	TGAI	10
850.1300 850.1350	Aquatic invertebrate life-cycle.	R	R	R	R	R	TGAI	TGAI	10
850.1500	Fish life-cycle	CR	CR	CR	CR	CR	TGAI	TGAI	11, 12
850.1710 850.1730 850.1850	Aquatic organisms, bioavailability, biomagnification, toxicity tests.	CR	CR	CR	CR	CR	TGAI, PAI, degradate.	TGAI, PAI, degradate.	13
850.1950	Simulated or actual field testing for aquatic organisms.	CR	CR	CR	CR	CR	TEP	TEP	14, 15, 16
Sediment Testing									
850.1735	Whole sediment; acute freshwater invertebrates.	CR	CR	CR	CR	CR	TGAI	TGAI	15, 17
850.1740	Whole sediment; acute marine invertebrates.	CR	CR	CR	CR	CR	TGAI	TGAI	15, 17, 19
None	Whole sediment; chronic invertebrates freshwater and marine.	CR	CR	CR	CR	CR	TGAI	TGAI	15, 18, 19

TABLE—ANTIMICROBIAL NONTARGET ORGANISM DATA REQUIREMENTS—Continued

Guideline No.	Data requirement	Use pattern					Test substance		Test note No.
		Industrial processes and water systems	Antifoulant coatings and paints	Wood preservatives	Aquatic areas	All other use patterns category	MP	EP	
Insect Pollinator Testing									
850.3020	Honeybee acute contact.	NR	NR	R	NR	CR	TGAI	TGAI	20
850.3030	Toxicity of residues to honeybees.	NR	NR	R	NR	CR	TGAI	TEP or treated wood.	20, 21

(d) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (c) of this section:

1. For industrial processes and water systems, antifoulant paints and coatings, wood preservatives, and aquatic areas, data are required for two avian species: one waterfowl species and one upland game bird species. For the all other use patterns category (as specified in § 158.2240(a)(5)), data are required for one avian species.

2. Data are required on one freshwater aquatic invertebrate species.

3. For the industrial processes and water systems, antifoulant paints and coatings, wood preservatives, and aquatic use pattern areas, data are required on two species of fish, one cold water species and one warm water species. For the all other use patterns category (as specified in § 158.2240(a)(5)), data are required on one species of fish, either one cold water species or one warm water species. Testing on a second species is required if the active ingredient or principal transformation products are stable in the environment and the LC_{50} in the first species is less than or equal to 1 ppm or 1 mg/L.

4. Data are required on one avian species, either one waterfowl species or one upland game bird species, if the avian acute oral LD_{50} (TGAI testing) is less than or equal to 100 mg/a.i./kg and a.i. residues or its principal transformation products are likely to occur in avian feed items. Data on the second species are required if the avian dietary LC_{50} in the first species tested is less than or equal to 500 ppm a.i. in the diet.

5. If TEP testing cannot be conducted due to the physical characteristics of the test substance (for example, a paint), then the applicant should request a waiver.

6. Data are required if one or more of the following criteria are met:

i. Birds may be subjected to repeated or continued exposure to the pesticide or any of its transformation products, especially preceding or during the breeding season.

ii. The pesticide or any of its major metabolites or degradation products are stable in the environment to the extent that a potentially toxic amount may persist in avian feed.

iii. The pesticide or any of its major metabolites or degradation products are stored or accumulated in plant or animal tissues, as indicated by the octanol/water partition coefficient (K_{ow} is greater than or equal to 1,000), accumulation studies, metabolic release and retention studies, or as indicated by structural similarity to known bioaccumulative chemicals.

iv. Any other information, such as that derived from mammalian reproduction studies, indicates that reproduction in terrestrial vertebrates may be adversely affected by the anticipated use of the pesticide product.

7. TEP testing is required for any product which meets one or more of the following conditions:

i. When based on deterministic modeling results: If the Estimated Environmental Concentration (EEC) in the aquatic environment is equal to or greater than one-half the LC_{50}/EC_{50} of the TGAI.

ii. When based on probabilistic modeling results: If the estimated 10th percentile 7Q10 Surface Water Concentration exceeds the acute concentration of concern (i.e., one-half the LC_{50}/EC_{50}).

iii. If an ingredient in the end-use product other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms.

iv. The end-use antimicrobial product will be applied directly into an aquatic environment.

8. Data are required on one estuarine/marine mollusk, one other estuarine/marine invertebrate, and one estuarine/marine fish species.

9. For the all other use patterns category (as specified in § 158.2240(a)(5)), industrial processes and water systems, wood preservatives, and aquatic areas, data are required if the pesticide residues from the parent compound and/or transformation products are likely to enter the estuarine/marine environment.

10. Testing must be conducted with the most sensitive organism (either freshwater or estuarine/marine vertebrates, or freshwater or estuarine/marine invertebrates), as determined from the results of the acute toxicity tests (acute EC_{50} freshwater invertebrates; acute LC_{50}/EC_{50} estuarine and marine organisms; acute freshwater fish LC_{50}).

11. Data are required on estuarine/marine species if the product is intended for direct application to the estuarine or marine environment, or the product is expected to enter this environment in significant concentrations because of its expected use or mobility patterns.

12. Data are required on freshwater species if the end-use product is intended to be applied directly to water, or is expected to be transported to water from the intended use site, and when one or more of the following conditions apply:

i. When based on deterministic modeling results: If the Estimated Environmental Concentration (EEC) in water is equal to or greater than 0.1 of the no-observed-adverse-effect concentration or no-observed-adverse-effect level (NOAEC/NOAEL) in the fish early-life stage or invertebrate life cycle tests.

ii. When based on probabilistic modeling results: If the estimated 10th percentile 7Q10 Surface Water Concentration based on probabilistic modeling exceeds for 20 days or more the chronic concentration of concern (i.e., one-tenth the NOAEC or NOAEL) determined in the fish early-life stage or invertebrate life cycle tests.

iii. If studies of other organisms indicate that the reproductive physiology of fish may be affected.

13. Not required when:

i. The octanol/water partition coefficients of the pesticide and its major degradates are less than 1,000;

ii. There are no potential exposures to fish and other nontarget aquatic organisms; or

iii. The hydrolytic half-life is less than 5 days at pH 5, 7, and 9.

14. Environmental chemistry methods used to generate data associated with this study must include results of a successful confirmatory method trial by an independent laboratory. Test standards and procedures for independent laboratory validation are available as addenda to the guideline for this test requirement.

15. Protocols must be approved by the Agency prior to the initiation of the study.

16. Data are required if the intended use pattern, and the physical/chemical properties and environmental fate characteristics of the antimicrobial indicate significant potential exposure, and, based on the results of the acute and chronic aquatic organism testing, significant impairment of nontarget aquatic organisms could result.

17. Data are required if the half-life of the pesticide in the sediment is equal to or less than 10 days in either the aerobic soil or aquatic metabolism studies, and if one or more of the following conditions are met:

i. The soil partition coefficient (K_d) is equal to or greater than 50 L/kg.

ii. The log K_{ow} is equal to or greater than 3.

iii. The K_{oc} is equal to or greater than 1,000.

18. Data are required if the EEC in sediment is greater than 0.1 of the acute LC_{50}/EC_{50} values and if one or more of the following conditions are met:

i. The soil partition coefficient (K_d) is equal to or greater than 50 L/kg.

ii. The log K_{ow} is equal to or greater than 3.

iii. The K_{oc} is equal to or greater than 1,000.

19. Sediment testing with estuarine/marine test species is required if the product is intended for direct application to the estuarine or marine environment or the product is expected to enter this environment in significant concentrations either by runoff or erosion, because of its expected use or mobility pattern.

20. For the all other use patterns category (as specified in § 158.2240(a)(5)), data are required only for beehive applications when the beehive (empty or occupied) may be treated.

21. A study similar to ''Honey Bee Toxicity of Residues on Foliage'' is required using treated wood instead of the foliage. Protocols must be approved by the Agency prior to the initiation of the study.

§ 158.2250 Nontarget plant protection.

(a) Subpart B of this part and § 158.2201 describe how to use the table in paragraph (f) of this section to determine the nontarget plant protection data requirements for a particular antimicrobial pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions are listed in paragraph (g) of this section.

(b) Data on transformation/degradation products or leachate residues of the parent compound are also required to support registration, if the transformation/degradation products or leachate residues meet one of the following criteria:

(1) More toxic, persistent, or bioaccumulative than the parent;

(2) Have been shown to cause adverse effects in mammalian or aquatic reproductive studies; or

(3) The moiety of concern (i.e., functional group in the parent chemical molecule that imparts adverse effects) remains intact.

(c) For the purpose of determining data requirements, the all other use patterns category includes the following use patterns:

(1) Agricultural premises and equipment.

(2) Food-handling/storage establishments, premises, and equipment.

(3) Commercial, institutional and industrial premises and equipment.

(4) Residential and public access premises.

(5) Medical premises and equipment.

(6) Human drinking water systems.

(7) Materials preservatives.

(8) Swimming pools.

(d) If an antimicrobial may be applied to a field crop, horticultural crop, or turf, then the data requirements in § 158.660 apply.

(e) *Key.* MP = Manufacturing use product; EP = End-use product; R = Required; CR = Conditionally required; NR = Not required; TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.

(f) *Nontarget plant protection data requirements table.* The following table shows the data requirements for nontarget plant protection. The test notes appear in paragraph (g) of this section.

TABLE—NONTARGET PLANT PROTECTION DATA REQUIREMENTS

Guideline No.	Data requirement	Use pattern					Test substance		Test note No.
		Industrial processes and water systems	Antifoulant coatings and paints	Wood preservatives	Aquatic areas	All other use patterns category	MP	EP	
850.4225	Seedling emergence, Tier II—dose response.	CR	CR	CR	CR	CR	TEP	TEP	1, 2
850.4250	Vegetative vigor, Tier II—dose response.	CR	NR	CR	CR	CR	TEP	TEP	1, 3
850.4400	Aquatic plant growth (aquatic vascular plant) Tier II—dose response.	R	R	R	R	CR	TGAI, TEP	TGAI, TEP	4, 10
850.5400	Aquatic plant growth (algal) Tier II (dose response).	R	R	R	R	R	TGAI, TEP	TGAI, TEP	4, 5, 6
850.4300	Terrestrial field	CR	CR	CR	CR	CR	TEP	TEP	7, 8, 9
850.4450	Aquatic field	CR	CR	CR	CR	CR	TEP	TEP	7, 8, 9

(g) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (f) of this section:

1. Data on only one plant species (rice, *Oryza sativa*) are required.

2. Data are required if the risk quotient from any aquatic plant growth Tier II study exceeds a level of concern for aquatic plants.

3. Not required when:

i. There are no potential exposures to plants;

ii. The hydrolytic half-life is less than 5 days at pH 5, 7, and 9; or

iii. The results of a biodegradation study indicate that the active ingredient or principal degradation products are not biodegradable in 28 days, i.e., the biodegradation curve has not reached a plateau for at least three determinations within the 28 days.

4. For TEP testing, data are required for the applicant's end-use product if an ingredient in the end-use product, other than the active ingredient, is expected to enhance the toxicity of the active ingredient.

5. One Tier II (dose response) study, conducted with *Selenastrum capricornutum,* is required for the all other use patterns category (as specified in § 158.2250(c)). If the results of this study exhibit detrimental effects (EC_{50} less than 1.0 ppm or mg/L), then additional Tier II (dose response) studies are required on three species (*Anabaena flos-aquae, Navicula pelliculosa, and Skeletonema costatum).*

6. For industrial processes and water systems, antifoulant coatings and paints, wood preservatives, and aquatic areas, Tier II (dose response) studies are required on four species (*Anabaena flos-aquae, Navicula pelliculosa, Skeletonema costatum,* and *Selenastrum capricornutum*).

7. Environmental chemistry methods used to generate data must include the results of a successful confirmatory method trial by an independent laboratory.

8. Tests are required on a case-by-case basis based on the results of lower tier plant protection studies, adverse incident reports, intended use pattern, and environmental fate characteristics that indicate potential exposure.

9. Protocols must be approved by the Agency prior to the initiation of the study.

10. For the all other use patterns category (as specified in § 158.2250(c)), data are required if the aquatic (algal) plant growth Tier II study demonstrates detrimental effects at less than 1.0 ppm or mg/L.

§ 158.2260 Applicator exposure.

(a) *General.* Subpart B of this part and § 158.2201 describe how to use the table in paragraph (d) of this section to determine the applicator exposure data requirements for antimicrobial pesticide products. Notes that apply to an individual test including specific conditions, qualifications, or exceptions are listed in paragraph (e) of this section.

(1) The Agency may accept surrogate exposure data estimations and/or modeling estimations from other sources to satisfy exposure data requirements. The surrogate data must meet the basic quality assurance, quality control, good laboratory practice, and other scientific requirements set by EPA. To be acceptable, the Agency must find that the surrogate exposure data estimations have adequate information to address the applicable exposure data requirements and contain adequate monitoring events of acceptable quality. The data must reflect the specific use prescribed on the label and the activity of concern, including formulation type, application methods and rates, type of activity, and other pertinent information.

(2) Occupational uses include not only handlers, mixers, loaders, and applicators, but also commercial applications to residential sites. Residential uses are limited to non-occupational, i.e., non-professional, antimicrobial applications. Both occupational and residential applicator data may be required for the same product.

(b) *Criteria for testing.* Applicator exposure data described in the table to paragraph (d) of this section are required based on toxicity and exposure criteria. Data are required if at least one of the toxicity criteria in paragraph (b)(1) of this section, and at least one of the exposure criteria in paragraph (b)(2) of this section are met.

(1) *Toxicity criteria.* (i) Evidence of potentially significant adverse effects have been observed in any applicable toxicity studies.

(ii) Scientifically sound epidemiological or poisoning incident data with a clear cause-effect relationship indicating that adverse health effects may have resulted from exposure to the pesticide.

(2) *Exposure criteria.* (i) Dermal exposure may occur during product use.

(ii) Respiratory exposure may occur during product use.

(c) *Key.* R = Required; CR = Conditionally required; TEP = Typical end-use product.

(d) *Antimicrobial applicator exposure data requirements table.* The following table shows the data requirements for applicator exposure. The test notes appear in paragraph (e) of this section.

TABLE—ANTIMICROBIAL APPLICATOR EXPOSURE DATA REQUIREMENTS

Guideline No.	Data requirements	Use sites		Test substance	Test note No.
		Occupational	Residential		
875.1100	Dermal exposure	R	R	TEP	1, 2, 3, 4
875.1200					
875.1300	Inhalation exposure	R	R	TEP	1, 2, 3, 4
875.1400					
875.1500	Biological monitoring	CR	CR	TEP	1, 2, 3
875.1600	Data reporting and calculations	R	R	TEP	5
875.1700	Product use information	R	R	TEP	

(e) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (d) of this section:

1. Prior to initiation of the study, protocols involving intentional exposure of human subjects must be submitted for review by EPA and then the Human Studies Review Board (HSRB) according to 40 CFR 26.1125. Examples of proposed human study research can be found in various reviews provided by the Human Studies Review Board (*http://www.epa.gov/osa/hsrb/index.htm*).

2. Biological monitoring data may be submitted in addition to, or in lieu of, dermal and inhalation passive dosimetry exposure data, provided the human pharmacokinetics of the pesticide or metabolite/analog compounds (*i.e.,* whichever method is

selected as an indicator of body burden or internal dose) allow for the back calculation to the total internal dose.

3. For products with both indoor and outdoor uses, and similar conditions of use, data are generally required for the indoor applications only. However, data for outdoor uses are required if the Agency expects outdoor uses to result in greater exposure than indoor uses (e.g., higher use rates and application frequency, or longer exposure duration, or application methods/equipment create potential for increased dermal or inhalation exposure in outdoor versus indoor use sites). In certain cases, when a pesticide may be used both indoors and outdoors under dissimilar conditions of use, the Agency may require submission of applicator exposure data for both use patterns.

4. EPA will consider waiving this data requirement for antimicrobials applied via closed loading systems if the antimicrobial has a low vapor pressure.

5. Data reporting and calculations are required only if handler exposure data are required.

§ 158.2270 Post-application exposure.

(a) *General.* Subpart B of this part and § 158.2201 describe how to use the table in paragraph (d) of this section to determine the post-application exposure data requirements for antimicrobial pesticide products. The data generated during these studies are used to determine the quantity of pesticide to which people may be exposed after application. Notes that apply to an individual test, including specific conditions, qualifications, or exceptions to the designated test, are listed in paragraph (e) of this section.

(1) Post-application exposure data are required when certain toxicity criteria are met and the human activities associated with the pesticide's use pattern can lead to potential adverse exposures.

(2) The Agency may accept surrogate exposure data estimations and/or modeling estimations from other sources to satisfy exposure data requirements. The surrogate data must meet the basic quality assurance, quality control, good laboratory practice, and other scientific requirements set by EPA. To be acceptable, the Agency must find that the surrogate exposure data estimations have adequate information to address the applicable exposure data requirements and contain adequate monitoring events of acceptable quality. The data must reflect the specific use prescribed on the label and the activity of concern, including formulation type, application methods and rates, type of activity, and other pertinent information.

(b) *Criteria for testing.* Post-application exposure data described in the table to paragraph (d) of this section are required based on toxicity and exposure criteria. Data are required if at least one of the toxicity criteria in paragraph (b)(1) of this section, and at least one of the exposure criteria in paragraph (b)(2) of this section are met.

(1) *Toxicity criteria.* (i) Evidence of potentially significant adverse effects have been observed in any applicable toxicity studies.

(ii) Scientifically sound epidemiological or poisoning incident data with a clear cause-effect relationship indicating that adverse health effects may have resulted from exposure to the pesticide.

(2) *Exposure criteria*—(i) *Outdoor uses.* (A) Occupational human post-application or bystander exposure to residues of antimicrobial pesticides could occur as the result of, but is not limited to, worker reentry into treatment sites, clean-up and equipment maintenance tasks, handling wood preservative-treated wood, or other work-related activity.

(B) Residential human post-application or bystander exposure to residues of antimicrobial pesticides could occur following the application of antimicrobial pesticides to outdoor areas and spaces at residential sites, such as, but not limited to homes, daycare centers, and other public buildings.

(ii) *Indoor uses.* (A) Occupational human post-application or bystander exposure to pesticide residues could occur following the application of the antimicrobial pesticide to indoor spaces or surfaces.

(B) Residential human post-application or bystander exposure to pesticide residues could occur following the application of the antimicrobial pesticide to indoor spaces or surfaces at residential sites, such as, but not limited to homes, daycare centers, hospitals, schools, and other public buildings.

(c) *Key.* R = Required; CR = Conditionally required; NR = Not required; TEP = Typical end-use product.

(d) *Antimicrobial post-application exposure data requirements table.* The following table shows the data requirements for post-application exposure. The test notes appear in paragraph (e) of this section.

TABLE—ANTIMICROBIAL POST-APPLICATION EXPOSURE DATA REQUIREMENTS

Guideline No.	Data requirement	Use sites		Test substance	Test note No.
		Occupational	Residential		
875.2200	Soil residue dissipation	CR	CR	TEP	2, 3
875.2300	Indoor surface residue dissipation	CR	R	TEP	3, 4, 5, 6
875.2400	Dermal exposure	CR	CR	TEP	1, 7, 8
875.2500	Inhalation exposure	CR	CR	TEP	1,7, 8, 9
875.2600	Biological monitoring	CR	CR	TEP	1, 8
875.2700	Product use information	R	R	TEP	
875.2800	Description of human activity	R	R	TEP	
875.2900	Data reporting and calculations	R	R	TEP	10

(e) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (d) of this section:

1. Prior to initiation of the study, protocols involving intentional exposure of human subjects must be submitted for review by EPA and then the Human Studies Review Board (HSRB) according to 40 CFR 26.1125. Examples of proposed human study research can be found in various reviews provided by the Human Studies Review Board (HSRB) (*http://www.epa.gov/osa/hsrb/index.htm).*

2. For residential wood preservative uses, data may be required if soil has the potential to be an important exposure pathway, and soil is in contact with or adjacent to treated wood, including but not limited to decks, play sets, and gazebos,

3. Protocols must be approved by the Agency prior to the initiation of the study.

4. For wood preservatives, data are required for treated wood surfaces where post-application contact with treated wood is anticipated.

5. For occupational uses, data are required if the pesticide may be applied to or around surfaces, and if the human activity data indicate that workers are likely to have post-application dermal contact with treated surfaces while participating in typical activities.

6. Data are required for residential use sites, schools, and daycare institutions. This includes but is not limited to the following: Residential and public access premises; material preservatives (including those used in residential products, including but not limited to clothing and plastic toys) and wood preservatives (when contact with treated wood is likely to occur).

7. Data are required for occupational and residential uses if the human activity data indicate the potential for post-application dermal and/or inhalation exposures while participating in typical activities and no acceptable modeling options are available.

8. Biological monitoring data may be submitted in addition to, or in lieu of, dermal and inhalation passive dosimetry exposure data provided the human pharmacokinetics of the pesticide or metabolite/analog compounds (*i.e.,* whichever method is selected as an indicator of body burden or internal dose) allow for a back-calculation to the total internal dose.

9. Data are required for occupational and residential uses if there is the potential for bystander exposure and the pesticide use could result in respirable and/or inhalable material (e.g., gas, vapor, aerosol, or particulates).

10. Data reporting and calculations are required only if post-application exposure data are required.

§ 158.2280 Environmental fate.

(a) *General.* Subpart B of this part and § 158.2201 describe how to use the table in paragraph (c) of this section to determine the environmental fate data requirements for antimicrobial pesticide products. Notes that apply to an individual test including specific conditions, qualifications, or exceptions are listed in paragraph (d) of this section.

(1) Environmental fate data are required to support the registrations of all end-use and manufacturing-use antimicrobial products.

(2) Data on transformation/degradation products or leachate residues of the parent compound are also required to support registration, if the transformation/degradation products or leachate residues meet one of the following criteria:

(i) More toxic, persistent, or bioaccumulative than the parent;

(ii) Have been shown to cause adverse effects in mammalian or aquatic reproductive studies; or

(iii) The moiety of concern (i.e., functional group in the parent chemical molecule that imparts adverse effects) remains intact.

(3) For the purpose of determining data requirements, the all other use patterns category includes the following use patterns:

(i) Agricultural premises and equipment.

(ii) Food-handling/storage establishments, premises, and equipment.

(iii) Commercial, institutional and industrial premises and equipment.

(iv) Residential and public access premises.

(v) Medical premises and equipment.

(vi) Human drinking water systems.

(vii) Materials preservatives.

(viii) Swimming pools.

(b) *Key.* MP = Manufacturing use product; EP = End-use product; R = Required; CR = Conditionally required; NR = Not required; TGAI = Technical grade of the active ingredient; TEP = Typical end-use product; PAIRA = Pure active ingredient radiolabeled; ROC = residue of concern.

(c) *Antimicrobial environmental fate data requirements table.* The following table shows the data requirements for environmental fate. The test notes appear in paragraph (d) of this section.

TABLE—ANTIMICROBIAL ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline No.	Data requirement	Use pattern					Test substance		Test note No.
		Industrial processes and water systems	Antifoulant coatings and paints	Wood preservatives	Aquatic areas	All other use patterns category	MP	EP	
Degradation Studies—Laboratory									
835.2120	Hydrolysis	R	R	R	R	R	TGAI or PAIRA.	TGAI or PAIRA.	1
835.2240	Photodegradation in water.	R	R	R	R	R	TGAI or PAIRA.	TGAI or PAIRA.	2
835.2410	Photodegradation in soil.	NR	NR	R	NR	NR	TGAI or PAIRA.	TGAI or PAIRA.	10
Toxicity and Fate in Wastewater Systems									
850.6800	Activated Sludge, Respiration Inhibition Test. OECD 209.	R	R	R	NR	R	TGAI	TGAI	21
835.1110	Activated Sludge Sorption Isotherm.	CR	CR	CR	NR	CR	TGAI	TGAI	19, 20
835.3110	Ready Biodegradability.	CR	CR	CR	NR	CR	TGAI	TGAI	3, 4, 18
835.3220	Porous Pot Study	CR	CR	CR	NR	CR	TGAI	TGAI	3, 18
835.3280	Simulation Tests to Assess the Biodegradability of Chemicals Discharged in Wastewater.	CR	CR	CR	NR	CR	TGAI	TGAI	3, 18

TABLE—ANTIMICROBIAL ENVIRONMENTAL FATE DATA REQUIREMENTS—Continued

Guideline No.	Data requirement	Use pattern					Test substance		Test note No.
		Industrial processes and water systems	Antifoulant coatings and paints	Wood preservatives	Aquatic areas	All other use patterns category	MP	EP	
835.3240	Simulation Test—Aerobic Sewage Treatment: A. Activated Sludge Units.	CR	CR	CR	NR	CR	TGAI	TGAI	3, 18
Mobility Studies									
835.1230	Leaching and adsorption/desorption.	R	R	R	R	CR	TGAI or PAIRA.	TGAI or PAIRA.	5, 6
835.1240									
Metabolism Studies—Laboratory									
835.4100	Aerobic soil metabolism.	CR	NR	R	CR	CR	TGAI or PAIRA.	TGAI or PAIRA.	7, 8, 9
835.4200	Anaerobic soil metabolism.	NR	NR	R	NR	CR	TGAI or PAIRA.	TGAI or PAIRA.	5, 8
835.4300	Aerobic aquatic metabolism.	R	R	R	R	CR	TGAI or PAIRA.	TGAI or PAIRA.	5, 8
835.4400	Anaerobic aquatic metabolism.	R	R	R	R	CR	TGAI or PAIRA.	TGAI or PAIRA.	5, 8
Dissipation Studies—Field									
835.6200	Aquatic (sediment).	CR	R	CR	R	CR	TEP	TEP	11, 12, 13
Ground and Surface Water Monitoring									
None	Monitoring of representative U.S. waters.	CR	CR	CR	CR	CR	ROC	ROC	11, 14, 17
Special Studies									
None	Special leaching	NR	R	R	NR	NR	TGAI	TEP	15, 16

(d) *Test notes.* The following test notes apply to the data requirements in the table in paragraph (c) of this section:

1. For testing antifoulant paints and coatings, testing is to be performed separately with both sterile buffered distilled water and sterile synthetic seawater at pHs 5, 7, and 9.

2. Not required if:

i. The electronic absorption spectra, measured at pHs 5, 7 and 9, of the chemical and its hydrolytic products, if any, show no absorption or tailing between 290 and 800 nm, inclusive; or

ii. The results of the hydrolysis study at all three pHs (5, 7, and 9) demonstrates a half-life of less than 30 days.

3. The results of the activated sludge, respiration inhibition (ASRI) test determine which of the following tests are required: Ready biodegradability, porous pot, the biodegradation in activated sludge study as described in the ''Simulation Tests to Assess the Biodegradability of Chemicals Discharged in Wastewater,'' or simulation test—aerobic sewage treatment: A. activated sludge units.

i. If the ASRI test EC_{50} is equal to or less than 20 mg/L, then the applicant must choose either to:

A. Conduct the biodegradation in activated sludge study as described in the ''Simulation Tests to Assess the Biodegradability of Chemicals Discharged in Wastewater'';

B. Conduct the porous pot test; or

C. Conduct the simulation test—aerobic sewage treatment: A. activated sludge units.

ii. If the ASRI test EC_{50} is greater than 20 mg/L, then the applicant must choose either to:

A. Conduct a ready biodegradability study; or

B. Conduct one of the following studies: The biodegradation in activated sludge study as described in the ''Simulation Tests to Assess the Biodegradability of Chemicals Discharged in Wastewater,'' the porous pot test, or the simulation test—aerobic sewage treatment: A. activated sludge units.

4. Pass criteria for the ready biodegradability study are: 70 percent removal of dissolved organic carbon (DOC) and 60 percent removal of theoretical oxygen demand (ThOD) or theoretical carbon dioxide ($ThCO_2$) production for respirometric methods. These pass levels must be reached in a 10-day window within the 28-day period of the test. If the antimicrobial passes the ready biodegradability study, then no further testing is required. If the antimicrobial fails the ready biodegradability study, then the applicant must conduct one of the following studies: The biodegradation in activated sludge study as described in the ''Simulation Tests to Assess the Biodegradability of Chemicals Discharged in Wastewater,'' the porous pot test, or the simulation test—aerobic sewage treatment: A. activated sludge units.

5. For the all other use patterns category (as specified in § 158.2280(a)(3)), data are required based on a weight-of-evidence evaluation of the results of the hydrolysis, photodegradation in water, activated sludge sorption isotherm, biodegradability, and activated sludge, respiration inhibition tests.

6. Adsorption and desorption using a batch equilibrium method is preferred.

In some cases, as when the antimicrobial pesticide degrades rapidly, soil column leaching with unaged or aged columns may be more appropriate to fully characterize the potential mobility of the parent compound and major transformation products.

7. For industrial processes and water systems, aquatic areas, and the all other use patterns category (as specified in § 158.2280(a)(3)), data are required based on a weight-of-evidence evaluation of the results of the hydrolysis, photodegradation in water, activated sludge sorption isotherm, biodegradability, and activated sludge, respiration inhibition tests.

8. The environmental media (soil, water, hydrosoil, and biota) to be utilized in these studies must be collected from areas representative of potential use sites.

9. For industrial processes and water systems, and aquatic areas, data are required for use sites that are intermittently dry.

10. Data are not required if the antimicrobial is an inorganic substance or a metal salt; or if the standardized soil profiles demonstrate that the antimicrobial is likely to readily degrade either microbially or via redox reactions (chemically) and no transformation/degradate/leachate products of concern (as described under § 158.2280(a)(2)) are produced.

11. Analytical methods used to generate data associated with this study must include results of a successful confirmatory method trial by an independent laboratory.

12. Protocols must be approved by the Agency prior to the initiation of the study.

13. For industrial processes and water systems, wood preservatives, and the all other use patterns category (as specified in § 158.2280(a)(3)), data are required based on the potential for aquatic exposure and if the weight-of-evidence indicates that the active ingredient or principal transformation products are likely to have the potential for persistence, mobility, nontarget aquatic toxicity, or bioaccumulation.

14. Data are required if the weight-of-evidence indicates that the active ingredient or principal transformation products are likely to occur in nontarget freshwater, estuarine, or marine waters such that human or environmental exposures are likely to occur. In making that determination, the Agency takes into account other factors such as the toxicity of the chemical(s), available monitoring data and the vulnerability of the freshwater, estuarine, or marine water resources in the antimicrobial use area.

15. For wood preservatives, an aquatic leaching study is required. A soil leaching study is required if human or environmental exposures are likely to occur from leachates that contain the active ingredient or principal transformation products from wood treated with a preservative product. Protocols must be approved by the Agency prior to the initiation of the study.

16. For antifoulant paints and coatings, a leaching study is required. Protocols must be approved by the Agency prior to the initiation of the study.

17. Protocols, which include the residues of concern (such as parent, degradate/transformation product, and/or leachate residues) that would be monitored, must be approved by the Agency prior to the initiation of the study.

18. A biodegradation study is not required if the antimicrobial meets one or more of the following criteria:

i. Classified as a metal,

ii. Relatively volatile, but not hydrophobic,

iii. Highly reactive,

iv. Both the parent and all transformation/degradate products (as described under § 158.2280(a)(2)) have half-lives of less than 3 hours,

v. None of the registered or proposed product uses would result in transport of the parent and its transformation/degradate products (as described under § 158.2280(a)(2)) to a wastewater treatment plant.

19. The activated sludge sorption isotherm test is not required if the antimicrobial is:

i. Relatively volatile, but not hydrophobic;

ii. Highly reactive; or

iii. The log K_{ow} is less than 3.0.

20. If the criteria of test note 19 of this paragraph are not met, then the activated sludge sorption isotherm test is required if one or more of the following criteria are also met:

i. The antimicrobial is a metal,

ii. The log K_{ow} is greater than or equal to 3.0,

iii. The antimicrobial is positively charged or polycationic,

iv. The EC_{50} in the activated sludge, respiration inhibition test is less than or equal to 20 mg/L,

v. The EC_{50} in the activated sludge, respiration inhibition test is greater than 20 mg/L, and the antimicrobial fails the ready biodegradability study.

21. The activated sludge respiration inhibition study is not required if none of the registered or proposed product uses would result in transport of the parent and its transformation/degradate products (as described under § 158.2280(a)(2)) to a wastewater treatment plant.

§ 158.2290 Residue chemistry.

(a) *General.* Subpart B of this part and § 158.2201 describe how to use the table in paragraph (h) of this section to determine the residue chemistry data requirements for antimicrobial pesticide products. Notes that apply to an individual test including specific conditions, qualifications, or exceptions are listed in paragraph (i) of this section.

(b) Residue chemistry data are required for:

(1) Antimicrobial end-use products with uses that may result in residues in or on food, including but not limited to:

(i) Products that require a tolerance, tolerance exemption, or food additive regulation or clearance.

(ii) Products that may be used to treat livestock or poultry drinking water, for food egg washing, or for fruit and vegetable rinses.

(iii) Products that may be applied to a surface or incorporated into a material that may contact food or feed. Data are required regardless of whether the antimicrobial is applied or impregnated for the purpose of imparting antimicrobial protection to external surfaces of the substance or article, or for the purpose of protecting the substance or article itself.

(iv) Products that may be applied to water that have the potential to result in residues in potable water, or in water used for livestock and poultry drinking water, irrigation of crops, or water containing fish that may be used for human food.

(v) Wood preservative or antifoulant products intended for treating submerged materials that may result in food contact (e.g., lobster pots, fish cages on fish farms).

(2) Each manufacturing-use product bearing directions for formulation into an end-use product bearing uses described in paragraph (b)(1) of this section.

(c) Residue chemistry data are not required under paragraph (b) of this section if no adverse effects (no toxicity endpoints) are associated with dietary exposure to the active ingredient or if theoretical (high-end) dietary exposure estimates combined with the applicable toxicity endpoint result in acute and chronic dietary risks that are below the Agency levels of concern.

(d) For purposes of this section, Magnitude of the Residue Studies include the following: Food-handling, migration studies, potable water, fish,

irrigated crops, meat/milk/poultry/eggs, crop field trails, processed food or feed, and anticipated residues.

(e) If the antimicrobial chemical may be applied to a field crop, then the residue chemistry data requirements of § 158.1410 apply.

(f) The following term is defined for the purposes of this section: *Residue of concern* means the parent pesticidal compound and its metabolites, degradates, and impurities of toxicological concern.

(g) *Key.* R = Required; CR = Conditionally required; NR = Not required; TGAI = Technical grade of the active ingredient; TEP = Typical end-use product; PAI = Pure active ingredient; PAIRA = Pure active ingredient radiolabeled; ROC = Residue of concern.

(h) *Antimicrobial residue chemistry data requirements table.* The following table shows the data requirements for residue chemistry. The test notes appear in paragraph (i) of this section.

TABLE—ANTIMICROBIAL RESIDUE CHEMISTRY DATA REQUIREMENTS

Guideline No.	Data requirement	Uses				Test substance	Test note No.
		Agricultural premise	Indirect food	Direct food	Aquatic		
Supporting Information							
860.1100	Chemical identity	R	R	R	R	TGAI	
860.1200	Directions for use	R	R	R	R		
860.1550	Proposed tolerance/tolerance exemption.	R	R	R	R		1
860.1560	Reasonable grounds in support of petition.	R	R	R	R		1
860.1650	Submittal of analytical reference standards.	R	R	R	R	PAI/ROC	2
Food-Contact Surfaces or Impregnated Materials							
860.1460	Food-handling	CR	CR	CR	CR	TEP	3
None	Nature of residue on surfaces	CR	CR	CR	CR	PAIRA or TGAI.	4
None	Migration studies	CR	CR	CR	CR	TEP	5
860.1340	Residue analytical method for data collection.	CR	CR	CR	CR	ROC	6
860.1380	Storage stability	R	R	R	R	TEP or ROC	7
Higher tiered							
860.1300	Nature of the residue in plants	CR	CR	CR	CR	PAIRA	8
860.1300	Nature of the residue in livestock	CR	CR	CR	CR	PAIRA	9
860.1340	Residue analytical methods for tolerance/tolerance exemption enforcement.	CR	CR	CR	CR	ROC	10
860.1360	Multiresidue method testing	CR	CR	CR	CR	ROC	11
860.1400	Potable water	CR	CR	CR	CR	TEP	12
860.1400	Fish	CR	CR	CR	CR	TEP	13
860.1400	Irrigated crops	CR	CR	CR	CR	TEP	14
860.1480	Meat/milk/poultry/eggs	CR	CR	CR	CR	TGAI or ROC.	15
860.1500	Crop field trials	CR	CR	CR	CR	TEP	16
860.1520	Processed food or feed	CR	CR	CR	CR	TEP	17
None	Anticipated residues	CR	CR	CR	CR	ROC	18

(i) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (h) of this section:

1. A petition proposing a numerical tolerance or a tolerance exemption is required for any food or feed use subject to section 408 of FFDCA if the use is not covered by an existing tolerance or tolerance exemption. If the use is subject to FFDCA section 409, the applicant must identify to EPA an applicable section 409 food additive regulation or clearance, or submit a copy of a petition to FDA requesting a section 409 food additive regulation or clearance for the food or feed use.

2. An analytical reference standard is required for any food or feed use requiring a numeric tolerance or exemption. Material safety data sheets as specified by the Occupational Safety and Health Administration in 29 CFR 1910.1200 must accompany analytical standards.

3. Data are required if a pesticide may be used in a food-handling establishment unless data including, but not limited to, theoretical (high-end) estimates, radiolabeled laboratory data, or the nature of the residue on surfaces study show that residues will not occur in food or feed.

4. If an antimicrobial pesticide may be applied to a food-contact surface or impregnated into a food-contact material and if theoretical (high-end) estimates of exposure exceed EPA's risk level of concern, then the nature of the residue on surfaces study is required. Protocols must be approved by the Agency prior to the initiation of the study.

5. Based on the results of the nature of the residue on surfaces study, if residues of concern are identified, then the migration study will be required. Protocols must be approved by the Agency prior to the initiation of the study.

6. If a magnitude of the residue study, as specified in § 158.2290(d), is required, then a residue analytical method suitable for collecting data is also required. The method must be capable of determining all residues of concern, to permit calculation of dietary risk or to establish a tolerance or tolerance exemption.

7. If a magnitude of the residue study, as specified in § 158.2290(d), is required, then storage stability data are also required, unless analytical samples are stored for 30 days or less. If, during hazard characterization, a residue has been identified as ''of concern'' and is known to be volatile or labile, then storage stability data are required regardless of sample storage time.

8. If crop plants or metabolically active raw agricultural commodities of food crops may be directly or indirectly exposed to an antimicrobial, plant metabolism studies are required to determine the transformation products that may enter the human diet. Such exposure could include, but is not limited to:

i. Treatment of storage or shipping containers,

ii. Postharvest fruit and vegetable treatment prior to shipping or storage,

iii. Use of antimicrobial-treated water for irrigation, and

iv. Any direct food contact use.

9. If livestock may be exposed to an antimicrobial, then hen and ruminant metabolism studies are required to determine the identities of residues of concern that may enter the human diet from consumption of livestock commodities. Livestock may be exposed via the oral, dermal, or inhalation route following treatment or contamination of sites including, but not limited to, livestock premises, feed, and drinking water. Shell eggs and other metabolically active livestock products may also be treated. If livestock may be exposed to one or more residues of concern differing from those found in animals, then one or more additional livestock metabolism studies involving dosing with these residues may be required.

10. If there is a numerical tolerance or tolerance exemption level to enforce, then a residue analytical method suitable for enforcement purposes is required. The method must be supported by an independent laboratory validation.

11. If there is a numerical tolerance or tolerance exemption level to enforce, then testing is required to determine whether the Food and Drug Administration/United States Department of Agriculture multiresidue methodology would detect and identify the antimicrobial and its residues of concern, as part of programs to monitor pesticides in the U.S. food supply.

12. Data are required if an antimicrobial may be applied directly to water or if there is the potential that the antimicrobial-treated water could be used directly for drinking water purposes by humans or animals or that contaminated water could run-off, leach, or be discharged from treated sites or materials and make its way into potable water.

13. Data are required if an antimicrobial may be applied directly to water inhabited by fish or that will be inhabited by fish or if contaminated water could run-off, leach, or be discharged from treated sites or materials and make its way into bodies of water containing fish that may be used for human consumption.

14. Data are required if an antimicrobial may be applied directly to water used for irrigation of food crops or such that contaminated water could run-off, leach, or be discharged from treated sites or materials to make its way into water used for irrigation of food crops.

15. If the antimicrobial may be applied directly to livestock, metabolically-active livestock commodities (e.g., eggs), livestock feed or drinking water, or livestock premises, or a livestock metabolism study indicates that residues of the antimicrobial may result in livestock commodities, studies are required to determine the magnitude of the residues of concern in fat, meat, meat by-products, milk, poultry, and eggs that may be consumed by humans. These studies, however, may not be required in cases where the livestock metabolism studies indicate that transfer of pesticide residues of concern to tissues, milk, and eggs is not expected to occur at the maximum expected exposure level for the animals.

16. If food crops or raw agricultural commodities of food crops may be exposed to an antimicrobial, then residue studies are required to determine the magnitude of the residues of concern that may enter the human diet. Such exposures include, but are not limited to, postharvest fruit and vegetable treatments and application of antimicrobial chemicals to field crops, mushroom houses, empty or occupied beehives, or wood used to construct beehives.

17. Data on the nature and magnitude of residues in processed food or feed are required if antimicrobial residues could potentially concentrate on processing. If so, the establishment of a separate tolerance higher than that in the raw agricultural commodity may be required.

18. Data are required when dietary exposure values at the tolerance level or screening-level (high-end) result in estimates of dietary or aggregate risk that meet or exceed the Agency's level of concern. These data may include, but are not limited to, washing, cooking, processing, or degradation studies as well as market basket surveys for a more realistic residue determination. Protocols must be approved by the Agency prior to the initiation of the study.

PART 161—[REMOVED]

■ 6. Remove part 161.

[FR Doc. 2013–10162 Filed 5–7–13; 8:45 am]

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FEDERAL REGISTER

Vol. 78 Wednesday,

No. 89 May 8, 2013

Part IV

The President

Proclamation 8975—National Charter Schools Week, 2013

Notice of May 2, 2013—Continuation of the National Emergency With Respect to Burma

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Presidential Documents

Title 3—

The President

Proclamation 8975 of May 3, 2013

National Charter Schools Week, 2013

By the President of the United States of America

A Proclamation

America's success in the 21st century depends on what we do today to reignite the true engine of our economic growth: a thriving middle class. Achieving that vision means making sure our education system provides ladders of opportunity for our sons and daughters. We need to equip all our students with the education and skills that put them on the path to good jobs and a bright future—no matter where they live or what school they attend.

Charter schools play an important role in meeting that obligation. These learning laboratories give educators the chance to try new models and methods that can encourage excellence in the classroom and prepare more of our children for college and careers. In return for this flexibility, we should expect high standards and accountability, and make tough decisions to close charter schools that are underperforming and not improving. But where charter schools demonstrate success and exceed expectations, we should share what they learn with other public schools and replicate those that produce dramatic results. Many charter schools choose to locate in communities with few high-quality educational options, making them an important partner in widening the circle of opportunity for students who need it most.

Our children are ready to write the next great chapter in the American story. As parents and teachers and citizens, it is up to all of us to provide them the tools they need to keep our country moving forward—from a degree that leads to a good job to the critical thinking skills that make our democracy thrive. This week, we recognize charter schools that are advancing those goals, and we recommit to helping our Nation's children go as far as their talents will take them.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 5 through May 11, 2013, as National Charter Schools Week. I commend our Nation's charter schools, teachers, and administrators, and I call on States and communities to support charter schools and the students they serve.

IN WITNESS WHEREOF, I have hereunto set my hand this third day of May, in the year of our Lord two thousand thirteen, and of the Independence of the United States of America the two hundred and thirty-seventh.

[FR Doc. 2013–11131
Filed 5–7–13; 11:15 am]
Billing code 3295–F3

Presidential Documents

Notice of May 2, 2013

Continuation of the National Emergency With Respect to Burma

Correction

In Presidential document 2013–10817 beginning on page 26231 in the issue of Monday, May 6, 2013, make the following correction:

On page 26231, on line 4, the Public Law number should read ''104–208''.

[FR Doc. C1–2013–10817
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